HIT Standards Committee
Draft Transcript
May 18, 2011

Presentation

Operator
All lines are bridged.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, operator. Good morning, everybody, and welcome to the 25th meeting of the HIT Standards Committee. This is a Federal Advisory Committee, so there will be opportunity at the end of the meeting for the public to make comment. Just a reminder for committee members to please identify yourselves when speaking, there is a transcript being made of the proceedings. Let's go around the table and introduce members, starting on my right with Josh Seidman.

Josh Seidman – ONC
Josh Seidman, ONC.

Elizabeth Holland – CMS – Director, HIT Initiatives Group, Office E-Health Standards & Services
Elizabeth Holland, CMS.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker, Geisinger.

Judy Murphy – Aurora Health Care – Vice President of Applications
Judy Murphy, Aurora Health Care.

Cris Ross – LabHub – CIO
Cris Ross, SureScripts.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Liz Johnson, Tenet Healthcare.

M
... Siemens Healthcare.

Linda Fischetti – VHA – Chief Health Informatics Officer
Linda Fischetti, VA.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Kevin Hutchinson – Prematics, Inc. – CEO
Kevin Hutchinson, Kevin Hutchinson.

John Halamka – Harvard Medical School – Chief Information Officer
Wow. I can't top that. John Halamka, Harvard Medical School and Beth Israel Deaconess.

M
Professor John Halamka.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jon Perlin, HCI, and faculty, Vanderbilt.

Farzad Mostashari – ONC – National Coordinator for Programs & Policy
Farzad Mostashari, ONC.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Dixie Baker, Science Applications International.

Stephen Ondra – NeHC – Senior Policy Advisor
Steve Ondra, the White House.

Janet Corrigan – National Quality Forum – President & CEO
Janet Corrigan, National Quality Forum.

Judy Sparrow – Office of the National Coordinator – Executive Director
And we have a number of members on the telephone. Wes Rishel, are you there? Stan Huff –

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
....

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay, that was Wes. Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes.

Judy Sparrow – Office of the National Coordinator – Executive Director
Nancy Orvis? David McCallie?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Derr?

John Derr – Golden Living LLC – Chief Technology Strategic Officer
Good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning. Anne Castro?

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect
Good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director
B.J. Lide, are you on for Cita Furlani?

B.J. (Bettijoyce) Lide – NIST – Scientific Advisor for HIT
Yes, I am. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Sharon Terry?

Sharon Terry – Genetic Alliance – President & CEO
Good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director
Anybody else on the telephone?

Martin Halwell
Martin Halwell.

Judy Sparrow – Office of the National Coordinator – Executive Director
Martin, welcome. And also, Carol Diamond just joined us at the table.

Walter Suarez – Kaiser Permanente
This is Walter Suarez with Kaiser Permanente, Judy.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay, thank you. And I'll turn it over to Dr. Mostashari.

Farzad Mostashari – ONC – National Coordinator for Programs & Policy
Good morning, everybody. This is Farzard. And I want to, first of all, acknowledge Dr. Halamka's homage in the form of wearing a bow tie today while I went with a straight tie.

John Halamka – Harvard Medical School – Chief Information Officer
I was shocked.

Farzad Mostashari – ONC – National Coordinator for Programs & Policy
I want to thank the committee and all the workgroups. We mentioned at our last meeting the incredible amount of work that's ahead of us, the "Summer of Fun", as Doug Fridsma calls it, and we're going to start to see some of the work that's in progress. I don't think we're going to have recommendations to review, at least too many of them in this meeting. But we're going to start to see some of the early work and the directionality for a lot of this, and it's really breathtaking in its scope. As we look across the report outs that are going to come initially, obviously one of the most important things that we collectively do is around the setting of the meaningful use with the Policy Committee guidance and then the certification criteria and the standards through this committee, the recommendations that come to the national coordinator and then to the secretary for endorsement. And we're going to hear about some of the particulars of directions where the Policy Committee has been considering in terms of keeping us moving up the escalator.

But as much room as there is to move providers and the industry really forward on meaningful use, so many of the discussions of the Policy Committee get into the issue of standards as well, saying that there is, even for areas where there were meaningful use standards already, meaningful use requirements in

Stage 1, there's still more work to be done on the standards side. And to move us continuously upward on that escalator in terms of having more interoperability, more protections for privacy and security, and better ability to take data and turn it into information that can be used to achieve our common goals of improving care within individual practices through things like decision support tools and registry functions and quality measurements that can help us create smarter payment methods that reward value over volume, as well as to start having us, as we were discussing in the Beacon meeting yesterday, start to play beautiful music together through care coordination and improved transitions of care. So the work here is so pivotally important to us achieving those goals.

And just reading down the list of things we're going to be dealing with on the privacy and security standards, today focusing a lot on interoperability and the variety of transactions and queries that we can move forward on, the Clinical Quality Workgroup, obviously quality measurement is such a critical expectation, I think, that the public and policy makers really have for us. The expectation is that as we go into 2015 and 2016 and 2017, as value-based purchasing begins to be implemented, as we have many of the accountable care organizations and all of the other aspects of better payment, smarter payment, that rely on quality measurement, the expectation from us is that we will deliver on that, that there will be a nationwide health information network that not only improves care for individuals, but helps us be able to see what we're doing and to be able to – as someone said, you can't fix what you can't see, so it really is our ability to see healthcare itself and to give providers the ability not only to have quality measurement done to them, but to have quality measurement done by them and for them.

The Implementation Workgroup is going to look at certification of the progress we've made in the temporary certification program, which we don't hear a lot about, and that's a very good thing probably, but now we're saying it's not enough for us not to have heard passively a lot of complaints, we want to hear, we really want to not just listen but we want to elicit what people's experience has been with the certification program and how we can improve it moving forward. And then clinical operations and vocabulary, to be able to, again, understand information after it's being – which I'm sitting next to Chris Chute so I have to say a little bit more than I otherwise would about how critically important that layer of semantic interoperability is to our ability to not only exchange information but understand information once it's exchanged.

I think the work that we're doing and really laying the path for the future, I see on the last part of the agenda some of the summer camp updates, everything from the metadata analysis, getting an early jump on that, giving early signals to industry on what those metadata standards might be and ability to see whether we can get early comment from the public on those data elements, patient matching, surveillance, ePrescribing, and NW-HIN. So a full agenda for today for the Standards Committee and I think, as we'll see, a full agenda for the whole summer. So I want to thank you all, and let's get to work.

I do want to welcome our newest member, Rebecca Kush, who's President and CEO of CDISC, which is an international non-profit organization which develops and supports global platform independent data standards that enable information systems interoperability to improve medical research. She holds a Ph.D. in Physiology and Pharmacology from the University of California. Welcome to Rebecca.

Let me turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you, Dr. Mostashari. Good morning, everybody, and thank you very much for being here today and continuing this incredible work. I think it was a terrific review of the agenda and a reminder of why we're all together, the bigger purpose. As someone in whose day life we are living the dream, trying to meet the impending activities or requirements of Stage 1, which, by the way, is 43 days until July 1st, for

those who might be counting, it is really an exciting time. It is, as you quite correctly said, Farzad, it is a time of ... and change. It is just exciting; exciting to begin to see the systems that come into place that support the vision that you articulated. It is an environment where people are also looking for the signals of what lies ahead, because indeed we have, as you well know, we have the health IT summer camp, Standards Committee, ONC summer camp of activities. I understand from Judy that Doug Fridsma will not only be coordinating that, but he is actually coordinating a number of ministerial duties of his office in flight back from Orlando, so hope that his flight is less eventful than some of ours. I know that this time of year does lead to a little bit of travel challenge, but I appreciate all of the members of the committee and the public who have joined, who made those connections and came out here this morning, or are joining online.

As always, the Office of the National Coordinator just does such an incredible job of synthesizing complex discussion into a cogent, mercifully brief summary of activities, and that is our cue to review the minutes. I will at this time ask you for any recommendations for amendments, corrections, ..., or otherwise. Hearing none, we will accept consensus on those, and again, thanks to the staff, Judy Sparrow in particular, for the terrific work and leadership.

I think Dr. Mostashari painted a wonderful picture of the things that will converge today. There's a lot of activity going on, a lot of activity between the meetings, so lots of the discussion we'll touch on today that also determines activity and convergence with our colleagues at the health IT Policy Committee and dovetail in terms of support for Stage 2 activities and the larger picture. Dr. Mostashari has painted the large picture, but I would ask my colleague, Dr. Halamka, if there are specific details that you'd like to focus our attention toward in today's agenda.

John Halamka – Harvard Medical School – Chief Information Officer
Absolutely. If we think about summer camp and the period from April to September, there's a series of tasks that we all have to accomplish to ensure that you have all the materials your office needs to get signed regulations written in time for the Meaningful Use Stage 2 deadlines. So let's just review the work that we're going to do over the course, April through September, and think about how it applies to the agenda today.

Remember, in April we finished the certificate management recommendations, Dixie has made a formal presentation about that, and in April we also said we were going to kick off some new teams, the metadata analysis team, looking at this universal exchange language and some of the headers that might be wrapped around existing transmissions, so that as we took the lessons learned in the PCAST Report we could actually have concrete recommendations to move forward. And so Stan Huff has chaired that activity, we've had a series of phone calls, you'll hear a presentation today as to where we are on the specific patient ID and provenance metadata, we've made some suggestions there. I think, Farzad, as you said, this is not a formal recommendation. It is giving you a preliminary report of suggestions and we have at least a relative framework, a charge, a scope of work on some of the privacy and security tags. We don't have an answer for you today, but we'll just show you the scope of what we're working on. We also kicked off the patient matching group, and so Mark is chairing that activity and you'll hear a brief report as to the scope of their work today.

Then for the month of May we said we would ensure we had a group kicked off for ePrescribing of discharge medications from a hospital, and Jamie is going to be chairing that activity, and I think in just a couple of calls you'll have some recommendations coming as to the possibilities for that. Also we said in the month of May we would look at preliminary vocabulary recommendations, so Jamie today will describe the work of the vocabulary taskforce, what in each domain it is looking at as that canonical standard for vocabulary and code set. We also said that in the month of May we would hear directory

recommendations on entity level provider directories, and you'll hear from Dixie and Walter today about that. They've actually gone through a series of meetings and have a series of standards recommendations for directories.

Then in June we said we would hear about the surveillance implementation guide. There are some calls that Chris Chute is going to be leading in getting us to a concrete implementation guide, where one does not exist today, on syndromic surveillance, that we would have direction on quality, recognizing that there were some improvements to be made and the ease of implementation of some of the quality measures, and Jim Walker is leading that activity. And that we would, in June, also begin that conversation about EHR/PHR data exchanges. And the Office of the National Coordinator is still working on leadership of that activity and how important it is to make sure that an EHR can transmit data to patients and families in a singular, consistent way as opposed to today where everything is a novel interface.

Then in July we will be taking on a review of the S&I framework activities, specifically lab simplification, transitions of care, and the clean-up of clinical document architecture standards, because there have been many implementation guides that need to be organized together into one that is hopefully quite usable. That also we would hear about some work on the Nationwide Health Information Network and its standards, and, Dixie, I believe you're going to be leading that discussion.

Then finally in August we would talk about distributed query standards. That if the notion is we're going to do public health, population health, clinical trials and clinical research, it would be wonderful that each of our organizations could provide a consistent interface so that we could discover associations between Vioxx and chest pain, or discover outbreaks of disease before they had actually become widespread and so we will have, I think, a robust discussion across a number of organizations who have already started to look at these kinds of distributed queries. In fact, there have been many news reports about whether it's CTSA or novel associations between Kaiser and Mayo and Geisinger and thinking about ways to start doing, not patient identified data exchange, but more working together to achieve mechanisms of data analysis ....

That is the summer. I think today's meeting, which exactly as promised will give us presentations on vocabulary and on directory and on metadata analysis is precisely aligned with the schedule that has been laid out by ONC. But we do need a check point today. We'd better make sure that everything we're doing across the summer is aligned still with the recommendations from Meaningful Use Stage 2 and the Meaningful Use Workgroup. So we will be starting the day with that summary from Paul and from George, because that's certainly an evolving set of work and with an evolving set of timelines and we want to be there with the standards they need so that the regulations can be completed in a timely manner. That's the day and that's the summer. We'll have fun.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, John. Indeed, a busy summer. Farzad?

Farzad Mostashari – ONC – National Coordinator for Programs & Policy
I just wanted to do a shout out to Doug Fridsma and the HL7 group that has been meeting, working on some of the difficult and thorny issues. What I said to Doug is we need it now and it also has to be mature and it has to be simple. So those are sometimes I think a seemingly impossible set of requirements to meet, but not just Doug and the S&I team but also so many of you as well as our partners on the standards development organization side are really embracing that challenge. I think in some cases the most difficult part of those three is the simple. When we are, I was reading a post recently about the 60 different flavors of null, and that's what you get when you have a very mature set of standards that have considered all the different extensions and situations where you might need it, and

yet at its extreme it then limits the ability for the standards to be used by all. That is really, one of our core principles is to make sure that the benefits of health IT can really reach all. And as we navigate between our eye on the prize and our feet on the ground, it's very important for us to design this in a way that is accessible and as simple as possible. So this is, I think, an additional challenge, an additional charge, but one that I'm sure the group collectively will be up for.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks for those words of wisdom, and I'd appreciate feedback if we deviate from trying to determine the most elegant and simple, vetted, tested, effective standards in support of the direction of your office and of our colleagues at the Policy Committee. Indeed, sometimes simple is harder, as is true in so many things. We will strive, though, for that degree of elegance in the work product. And I think what encourages me is looking around this table at not only the great leadership who are part of the committee, but also the networks of individuals who provide input, including from the public, to hold our feet to that task.

With that in mind, let's then segue to what the markers are that are being set for the next phase of activity, and I'm so pleased that Josh Seidman is here in the room with us to lead part of the discussion. Judy, we do have Dr. Paul Tang and Dr. George Hripcsak on the line to take us through an update on Stage 2 of Meaningful Use. Good morning.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good morning. Can you hear me?

Jonathan Perlin – Hospital Corporation of America – CMO & President
We can, indeed.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
This is Paul Tang. Thank you very much for the opportunity to provide an update on our Meaningful Use Stage 2 work. Both John and Farzad talked about a dizzying array of activities going on at HHS, ONC and in these FACA committees, and Farzad, when he talks about "It's not a sprint, it's a marathon." It's really a marathon of sprints for sure, and everybody really is up to the task.

This reminds me of my older daughter, who's finishing her first year of vet school at UC Davis, and while physicians in training certainly understand how much material there is to learn about one species, I'm really humbled by vet students, who have to learn the entire animal kingdom. But my wife and I always tell her when she looks so exhausted that, well, she's living her lifelong dream. So as you said, John, this is a lifelong dream that folks in this field have wanted to take advantage of this kind of technology, this infrastructure to serve a higher cause, and that's improved the health and healthcare of individuals .... So we're living the dream. If we can go to the next slide, please.

What we're doing is we're going to update you on some of our latest discussions with the HIT Policy Committee, and we're not through yet, we're going to be delivering our final recommendation in the June meeting, so we want to keep you informed because of the interdigitation between our work. First, let me point out the marvelous people on this workgroup who over the past over two years have been always head down, trying to make sure that we've balanced the tension between, as Farzad puts it, the eye on the prize and having our feet on the ground. So we, every meeting try to do that balance and keep it high on our mind. These are the members that have been so dedicated in meeting. In fact, last week we met three times. Next slide, please.

This, again, is the agenda that we showed to the HIT Policy Committee, which we're going to go over in quick fashion just to keep you informed, get your additional feedback, and see how the HIT Standards Committee interacts with the proposed or the draft recommendations as they're evolving. Next slide, please.

This is the work plan we've had over the last year. We had a number of hearings to flesh out some of the various perspectives, whether it's from specialist ..., healthcare disparities, patient and family engagement, population and public health, and care coordination. In fact, we wanted to fill out our knowledge base about the different perspectives as we move towards Stage 2 and Stage 3. We put out an RFC that we talked about with you last time and got back a number of comments. Those were ... by the ONC staff and taken as input by the workgroup as we try to reconcile the public input with our draft from December. We then updated last week the HIT Policy Committee, got further feedback from them and then on May the 13th had an additional hearing where we met with other specialists, as well as gotten some very interesting, and frankly somewhat gratifying feedback from the field from some of these early adopters. So as I said, we're moving towards a June 8th presentation to the HIT Policy Committee for final approval as we move that towards CMS and ONC. Next slide, please.

So we'll go through these slides very quickly. Again, this is an update, this is work in progress. I want to entertain your general questions about the philosophy and the approach that we're taking, but it's not ready yet, as you saw ... for recommendations going forward to HHS. In this first slide we're talking about the category of improving quality, safety, and efficiency and reducing healthcare disparities, and ideally, of course, eliminating healthcare disparities. I'll comment on some of the principles as we go. In this first one, computerized provider order entry, as you know, that's one of the cornerstones of this whole program. That's one of the best opportunities that we have for shaping the decisions that are made in an individual's care. We got a lot of strong public feedback supporting this, recognizing it's important, and so we've moved the threshold from 30% to 60%. Now, originally it was just covering medication orders, and in Stage 2 what we're proposing is to add another two important categories: laboratory orders and radiology. You'll see in red, the code here is blue is new functionality compared to Stage1, and red are some edits we made as the result of the public comments, and the comments we got from the Policy Committee.

In this case I'll mention one of the principles we started to use to ... radiology in use, and that is greater than or equal to one order. You might think, well, that's not that quite a tall order, but our approach was trying to reduce the burden on providers in meeting the meaningful use criteria, and we heard feedback about what's in the denominator, what counts, when in actuality once you have functionality turned on it's hardly in your best interest to keep it on just for the sole purpose of either meeting meaningful use criteria or reaching your floor. People are going to rapidly, in our mind, want to progress because this is a valuable tool anyway. So that's why we've basically, once you start using this tool for making orders to radiology, you're going to continue to use it. The worst and most painful point to be in is the hybrid where you're both paper and electronic. So we see this as just saying it's a way of expressing in use. It's a countable number, rather than a numerator, denominator.

In drug-drug interaction we're faced with, the challenge of the current state, as this committee knows, is one of high false positives. And that hurts not only the drug-drug interaction support, but it hurts just the end user's attitude toward the alerts it gets back from the system. It sort of desensitizes these. So we're intently interested in ways to improve the positive predictive value of these alerts. Ideally, there could be some nationally maintained list of very important and high impact alerts that we could all adopt and it would be maintained. That doesn't exist yet, but that in our minds would be something we'd love to achieve by Stage 3, just not ready for Stage 2. So we're moving on towards being able to have the local institution not just take the medication database that's available commercially, but also decide what's

important to it. There are certain high priority, high prevalence prescriptions that have a chance of interacting unfavorably and you know which ones those are and can give that additional prominence. That's the temporary state that we're in.

The next one has to do with just modifying the threshold from 40% to 50% for electronic prescribing, but also adding new functionality typically in the hospital arena. That is, when you're being discharged from the hospital those prescriptions obviously are going to outside pharmacies and we'd like to give that transaction the benefit of support from HIT, so we're starting out at a lower threshold because that is new functionality.

The next point has to do with demographics, and as you all know the importance of race, ethnicity, and language, that's one that if we don't measure it we'll have no way of understanding what disparities we may have and addressing those. We started out with the OMB categories and after the publication of Stage 1 recommendations the Institute of Medicine came out with a study that pointed out the importance of more granular categories of race and ethnicity in particular. So that's the direction we're heading. IOM recommendations included requesting that they suggest developing standards for these more granular categories and so we would hope to take advantage of them, at least by Stage 3. We wanted to use them in Stage 2 but right now, at least our understanding is that we don't have the standards in place, and that's something we'd appreciate your comments on.

The next three items are unchanged. Next slide, please. Med allergies are also unchanged. In the vital signs, in particular the blood pressure, we made a technical correction. We got feedback from the pediatricians that really the blood pressure for kids really isn't relevant until three years of age, so we made that technical correction as a proposal.

Smoking status, which is the next item, we recognize the importance of secondhand smoke. Clearly, there's an evidence base of how important that is in an individual's risk factors, and although we'd like to introduce that at this point, the standards don't exist for that, and so what we're signaling is that we'd like standards to be developed so we can add that in Stage 3.

The next item has to do with clinical decision support. Remember that we said, well, you ought to have one rule in Stage 1, clinical decision support can take many forms and we want to be able to support that and support innovation in this area, and it can be everything from coloring your choices that appear, to an alert in your face. So we came up with attributes, and we discussed this last time, attributes of what would be supporting clinical decisions being made. And we had some additional proposed revisions to those and we accepted those, and I'll go ahead and read those to you because you may want to comment in terms of how would you describe clinical decision support.

One, the EHR provides a message explaining to the provider the source citation of the CDS. Two, that it allows the rules to be configured to enable CDS based on a patient's context, i.e. clinical visit, being currently admitted. Third, that the ... information in the chart are about the patient's problems, allergies, medications, demographics, and vitals. Fourth, that the rules be configured to present decision support at a specific time, a relevant time in the clinical workflow, not just at some random time. It's presented at the time when they're most interested and can take immediate action. Fifth, that the rules allow there to be configured for users of certain roles, so a clerk wouldn't be getting the clinical alert that a clinician would get. And finally that the CDS be integrated with other applicable EHR functionality, can it bring up the right resource at the time you're providing an alert.

Those are examples of ways you would characterize CDS support, and anything meeting those we would propose would give you "credit" in providing clinical decision support. That, again, along with CPOE are two of the most important and powerful ways that these ... influence the care.
The next one is ... formulary. This is starting to go from something that was a menu item and the proposals that all the menus then become core, that's how the final rule read as well, and we're just introducing the notion that formularies, we got feedback that not in every part of the country and not for every drug do you know whether something is on a formulary. And you also don't necessarily have the latest information about an individual patient's insurance plan. So one approach that many people take is to know who the high prevalence insurers are in your area and you may choose some of the high prevalence drugs that are prescribed where there may be an alternative choice that the organization's decided is either equal or better. This proposal says that you should be able to use your local choice, ... that counts as a formulary not just external PBM formularies.

The next one has to do with advanced directive. Tony Trenkle at CMS warned us and it's true that this is an area that's really hard to get right, and we're making additional corrections as we move from menu to core, so, one, we think that for half of the patients in the hospital, where the patients are older than 65, at least we should have discussed advanced directives with them. One of the things we're adding is, and if the list as expected has taken place and an AD does exist, well then it should be available to the people who need to use it, i.e. who would scan that in, because most people are not going to act based just on an indication that such a discussion was had.

We're also proposing to include the EPs, because clearly the eligible professionals are the people who have much more of an ongoing relationship and are in a far better position to discuss this important matter with the patient. So we're starting out with a low threshold because, well, they may have had the discussion but they need time, or they already have this document but they don't have it with them in the office. There are a lot of reasons why you wouldn't have this 100% of the time for the patient ... in the reporting period. We started out with a low threshold, but the idea is to move us in the direction of having this important information, the patient's wishes, to be with them wherever they may contact a healthcare delivery system. We are asking for more information about, well, what's the current status of this kind of information, and particularly in the EP record, so that we don't inadvertently set a threshold that's not with our feet on the ground.

The next one has to do with clinical lab results. And again, we would really appreciate your guidance here. We've been informed that although LOINC is an adopted accepted standard, it's not always used, and we also know that there is no LOINC code for every procedure, so your advice on how do we set up the list perhaps of LOINC codes that you would like to make sure are in every certified EHR and move that into a requirement so that we have a uniform field where everybody has LOINC codes and can take advantage of them, whether it's in clinical decision support or it's being able to compare results from one organization to another.

One of the issues is that a large percent of laboratory tests are performed at hospitals for the EPs, and yet hospital labs may be one of the offenders who do not routinely include LOINC codes with the results. And although we do not have, as part of the meaningful use program don't have any levers with the commercial labs, we're trying to use this meaningful use requirement as a lever with the hospital lab to try to make sure that LOINC codes include .... Next slide, please.

Finally, we didn't make any change in the patient list. For the reminders, we tried to simplify the percentages. Instead of saying 20% of unique patients who are 65 or older or 5 years or younger, we said for all of your active patients, and we recognize we have to define active patients, that it might be like something people you've seen in the past 24 months, that 10% of that base surely has something to be

reminded about and, by the way, it's not an appointment reminder, something clinical having to do with their health that you can remind them about, whether it's health maintenance or follow up.

The final three items are new, and we did talk about them, in the last go-round with Stage 1 it didn't make it, so we'd like to propose that they be added to Stage 2. One has to do with essentially progress notes, strong support from the public about this, so on caveat saying, well, just a scanned handwritten note does not count, and we completely agree with that sentiment, these are electronic notes, transcribed reports are fine, things that can be searchable is the goal here.

The next one has to do with the electronic MAR, electronic medication administration record. Because medication errors is an important safety issue, both in the inpatient and outpatient setting, and this is proven technology, we wanted to start moving that into the hospital setting. And we're using the in-use kind of definition, that is, it's in use in at least one of the wards or units and we know that people are not just going to stop and say, hey, let's leave it there, because that fulfills the meaningful use criteria. People who are implementing the stuff are doing it so that they can improve care and they're not going to stop just because we set a floor.

Finally, at least in this category, we did receive a letter from NIH asking us to include family history because it's a very important indication of health risk for an individual. And we agree with that because ... the standards in this area, almost all EHRs have family history but it's done on an individual level. We all define our own code for those. So we'd ask your help in either anointing a standard or trying to influence one to be created in this area so we can use that in Stage 3. Next slide, please.

As we move over to the next category dealing with engaging patients and families, I'm going to turn it over to George to review some of our draft recommendations in those areas.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Thank you, Paul, very good. This is George Hripcsak. Judy, can you hear me?

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes, we can hear you.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Great. So for engaging patients and families one of the things we wanted to accomplish was to simplify sharing of information with patients. We found on the request for comments that in some cases we couldn't tell which comment went with which objective, which showed that there's some ambiguity and overlap among them. So therefore what you're seeing here is a clarification of that framework. The first objective, which is to provide electronic copy of health information, has been dropped, for two reasons. One, the essence of it is covered under the other objectives, and number two, to the extent that it's a legal requirement to share a legal copy of the record, it's covered under HIPAA and other regulations, and we want to focus on the clinical care and quality and not so much on legalities and regulations.

So then we move to our framework. Now, one way to look at it is that you have hospitals and eligible professionals, so you have two groups, and within each group you want to do two things: you want to have immediate information that's very relevant to their last visit that they just had, and you want a little bit more longitudinal data, so that results in four objectives total, two times two, and those are the next four objectives. The first one for eligible hospitals, and I should comment, we came up with a new metric. In some cases it's difficult to come up with either the numerator or the denominator, so in those cases we have two criteria. Number one, it's difficult to come up with a measurement, and number two, our assumption is that if someone's going to implement a sufficient number of them, they're going to tend to

do the whole thing and go to 100% as much as possible, and that we don't need to measure every last bit of it. And in those cases we came up with a metric where you just need to do 25 of them, at least 25 being the number that if you get that far you're probably going to go all the way with it. But this objective says that for hospitals at least 25 patients receive electronic discharge instructions at the time of discharge. It was hard to measure because it was hard to count what percentage of patients did not want electronic versions but perhaps wanted it on paper, and that's why we moved to the 25 number here. This is the immediate thing that's relevant to a patient.

Then the more longitudinal part is that 10% of patients or families view and download relevant information about a hospital admission, and that information's available within 36 hours of the encounter. This is a broader view of the entire admission, which includes information that's not immediately what do I need to do next, but might be useful for you, first of all, to understand what happened during hospitalization and perhaps share it with providers and so forth.

Then for eligible professionals, the longitudinal one is listed first here. For eligible professionals 10% of patients and families view and download longitudinal health information where information is available to all patients within 24 hours of an encounter. Let me clarify here, the 24 hours refers to information that's already there available to the healthcare provider and should be pretty much available quickly to the patients who just want to view it. In other words, there shouldn't be a long delay. What's not shown here but should be, and will be in the future version of the presentation is that there's still that four day grace period that if you just receive a lab result you still have time to review it before putting it out to patients.

The next objective is the short term one for eligible professionals, namely, 60% of patients are provided a clinical summary after all visits within 24 hours, with the exception that pending information, such as lab results, has four days. This is just a continuance of the Stage 1 objective with some change in the timing, that is, that stated authority available should be available quickly, although we recognize the problem of lab results.

Our next objective relates to educational resources for both EPs and hospitals, that 10% of patients receive EHR-enabled patient specific educational resources. Instead of increasing the threshold here we got rid of the word "if appropriate," and that just makes it easier to measure and we kept the threshold at a low level of 10%, and this is now core. Then three new objectives, for eligible professionals patients are offered secure messaging online in at least 25, it should say "greater than or equal to" there, 25 patients are sent secure messages online, again, not knowing how many patients might want to do this, trying to keep it as a low number just to prove that you can do it you have the technology in your EHR to do it and you implemented it at your site.

The next one is patient preferences for communication medium recorded at 20% of patients. Finally, a signal for Stage 3 to provide a mechanism for patient entered data and consider, and we'll need to supply that list. We need to start working on that now in preparation for Stage 3, and consider information reconciliation, that is, where patients can correct their errors again for Stage 3. Can I have the next slide, please?

For care coordination, here too we wanted to simplify, in Stage 1 we were performing tests, here we're trying to move towards actual use. The first objective, which was an infrastructural objective, we propose eliminating that, which was the test, in favor of actual use cases in the objectives that follow, the first one of those being medication reconciliation being conducted at 50% of transitions by the receiving provider and moving that to core. I apologize for the 80%. The red is the modification, and so it's ... the 80%, and we'll fix that. These are the slides we presented before, so it's unfortunately the second time I'm presenting a typo.

The next objective is a summary of care record, which we've left as we proposed, 10% of all discharges have summary of care records sent electronically to the EP or long term care facility, and for the EP, at least, again, going to the 25 transactions sent electronically. If it so happens, because for some EPs they're in a location where there's no one listed electronically, if that's the case then the exclusion doesn't exclude you from the objective, it excludes you from doing it electronically and you then must do it on paper. We just note here that we need a preamble to this explaining the role of HIE in this objective. A new one follows is a list of care team members available for 10% of patients, it should be 10% that have a list of care team members, including the PCP, if that's available in Stage 2 using unstructured data, because we don't think the standards for defining providers in a coded way are ready yet, so we did that in unstructured data in Stage 2, and hopefully structured by Stage 3.

And finally, this is a switch for the longitudinal care plan we proposed to merge. So we had proposed a longitudinal care plan because we believe it's very important to coordinate care. We're feeling for Stage 2 that we should merge this with a summary of care, which is the third one on this list, to create, instead of summary and care plan, which is the old summary plus fields for the plan and fields for patient engagement. There are two aspects of this, which is defining exactly which fields we're talking about. The second one is defining the workflow, that is, for Stage 2 is it only a push of the summary of care record, is it a pull for the summary of care record, or is it a collaborative document? I believe at this point that we're talking about probably not feasible to do a collaborative document at this point. We look forward to that in Stage 3 perhaps, and for now just transferring this summary and care plan. Can I have the next slide, please?

For population and public health, we previously had three objectives. The main change here, as you'll see, is moving from testing in Stage 1 to actually use, if possible, in Stage 2. So submit immunization data attesting to at least one transaction, again, on the theory that in fact not only would you do it if you can, but it's likely required by local law if you can do it. So in accordance with applicable law practice, moving this to core for both hospitals and professionals, with a signal to viewing ... for the payoff in Stage 3, which is cumulative immunization record and recommendations, that is, public health department generated recommendations that come back to the provider.

The second objective is that hospitals are submitting reportable lab results attesting to doing this with at least one organization, because there may be more than one public health organization that requires admission of the lab results and doing it with at least one electronically, again, in accordance with applicable law and practice and moving that to core. And for eligible hospitals, in the third one, submitting syndromic surveillance data, again, moving from test to actually doing, attesting to at least one in accordance to law and practice.

For professionals we're asking CMS to consider a similar objective for them. One way to do this would be to make it a menu item. You'll notice I haven't talked about menu items yet because we don't have any of the menu items. The problem with having one menu item is that it's either required that you do one, in which case its core, or you don't require it, in which case it doesn't exist. So if CMS decides to make several things menu then this could be one of them, would be one way. I'm talking specifically about the professional at the hospital here.

The next objective is in a similar category where we're ..., so that it might be a menu item, or at least for CMS to consider it, again, this is for Stage 2, submit a reportable condition in accordance with law and practice. Then looking to the Standards Committee that in fact ... Art Davidson worked on this, and so what is something that's really ready for this, that both has a potential standard available and that is

sufficiently important to manage population health by public health departments, and we came up with cancer conditions, because of the IHE cancer reporting implementation guide.

Then the final objective, this is a signal for Stage 3, which is patient generated data submitted to public health agencies, and it parallels the previous patient generated data in the patient engagement slide. Can I have the next slide, my last slide at least, privacy and security.

First of all, we continue to perform or update at this point security risk assessment and address deficiencies and propose to add to this addressing the issue of encryption of data at rest and then attesting to having a policy. So we're not suggesting that at this point in time we can mandate that all data at rest needs to be encrypted. What we're potentially mandating is that there needs to be a policy of if there's data at rest that's not encrypted, why is that and when did it get destroyed and so forth.

The next section, now, this is coming from the Tiger Team that was previously, not in this last meeting, but previously voted on by the Policy Committee, is a list of issues that I won't read right now, that are related to certification that we want to signal that we recognize these and we feel they're important, so that's the next row. The final row is signaling Stage 3 plans about the Nationwide Health Information Network governance. Next slide, please.

I'll turn it back to Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, George. I think everybody in the room of course knows that timing, particularly as we move from Stage 1 to Stage 2, has been a concern. I think overall the program is aggressive, but rightfully so, because it's not the legislation we're trying to keep up with, it's the needs of health reform and health delivery that we need to keep up with. That's the overall driver for our timing. And I want to thank Farzad for providing this insight in the highlighted cell here. When we talk about the conundrum of having the transition of Stage 1 to Stage 2, putting everybody in a shift overnight kind of spot, it's really affecting only one group of folks. So again, remember that we have our recommendations going to HHS, they go ... to an NPRM process at the end of the year and issue their final rules, anticipated to be middle of 2012. Well in theory for this first group, those that enter in 2011, the hospitals at least could be needing to start the reporting period as early as October of 2012 with a 2013 year. So that would leave almost no time for a combination of the vendors to develop new functionality and for the provider to implement, train, and get that up into meaningful use. That has been a challenge that just seems unworkable. But it's really only that cell that's highlighted that is affected by that short timeline, so one possibility is to just shift that one back. Next slide, please.

I think we even talked last time about some of the options for how to deal with this aggressive timeline while preserving the momentum of the program. So here are the three. There was a fourth one but we found that that perhaps was too complex and could be addressed by number three. The first one was maintain ... growth, with the current timeline, it goes into effect in 2013, October 2012 for hospitals, and it's a one year reporting period. Modification, or option two, is the same timeline but instead of a one year reporting period it is shortened to 90 days, just like it is in Stage 1. And of course what that does is it gives sort of a nine month additional time for the provider to implement the functionality before starting to report on it. Option three is to, in a sense, delay that transition from Stage 1 to Stage 2 by one year, which in effect only affects that one cell, the early entrants, the 2011 entrants.

So we came up with a number of factors to consider as you ponder these different options, and we were open to new other innovative options for maintaining the momentum yet dealing with some of the timing considerations. One is we absolutely have to get this HIT structure in place because the health system needs it in order to improve care in the ... population, so clearly, if everything were able to move in this timeline that would be the best choice, and that's option one.

The second consideration is we require new functionality, and certainly we've proposed some new functionality, then there's a finite time but then there's a need to spec it out, develop it, test it, and deploy it to all those customers. So you can see that in order then option one is the most aggressive and potentially infeasible for vendors to develop this new functionality, and then option three, of the three options that we're showing, has the most flexibility. Similarly, in the next row, provider implementation timeline, and unfortunately these two things the vendor development and the provider implementation has to happen in sequence. They can't happen in parallel. So likewise, option one is the most constraining and option three provides the most flexibility. We also recognize, and that's why we called out as a separate row of characteristics, is this ICD-10 deadline, October 1, 2013, and of course not everybody's going to implement September 30th, you've got this whole almost year before that when you're really in the process of doing various things. So again, option three probably gives you the opportunity, the most flexibility to sync up your upgrade, and all of these represent upgrades to your system for ICD-10 and for Meaningful Use Stage 2.

The next one has to do with just the operational complexity of operating the system, either from CMS from the Medicare side or states for the Medicaid side. And we saw option two where you're saying in this case we have three different possibilities, you've got the folks who are in the 90 day Stage 1, in option two you might have folks who are in a 90 day Stage 2 and so on and so forth, and it just becomes a little bit unwieldy.

The next attribute is the probability of our recommendations standing in the final rule. It doesn't really do anybody any favor by saying here's our aspirational goal that we know nobody can achieve. Clearly CMS is not going to come out and suggest that in the final rule, so why don't we try to be as in line as possible with where we think is the balance between the eye on the prize and the feet on the ground coming up .... And in our mind, and this is the workgroup speaking, of the three options that we currently have on the table three probably is the most likely that, one, it addresses that timing ... in that one ... as well as it appears to keep the momentum going.

If you look at that whole matrix and just scan the pluses and the minuses, our bottom line was this maintaining the meaningful use pace up the escalator. We want to maintain the momentum, but we want to get some of this important functionality that we're suggesting for Stage 2 in there because care coordination, health information exchange, is part of our top priority in this stage. If you scan that chart, it seems like the relative merits of the different options are shown in that bolded last line, and we tend to favor option three. Next slide, please.

Our next step, we had the hearing and it was really a good hearing on specialists and experience from the field, and I'll give you a bottom line comment from our last panel, which was experience from the field, they talked certainly about the time, the effort, and the sweat equity that goes into implementing Stage 1. But without exception, whether it was the ... or the largest health system, in fact, I asked the question, is there anything that we should give up because the burden just is not outweighed by the benefit to the system. To a person no one said they would give up anything. In a sense, they said it was all worth it because they, in fact they said they were already getting the benefit from doing that. So it's hard work, but they, again, from the large system to the ... clinic, thought that this is something they had to do to execute the core mission.

So that was incredibly gratifying for the committee and the workgroup of course. We recognize that this is a ... group that have done this early, but it's certainly a sentiment worth appreciating. We're going to incorporate the feedback we got from the Policy Committee, from the hearings, and start working on this over the next few weeks before we present our final recommendations to the HIT Policy Committee for approval on June 8th. That will get turned over into final recommendations going to CMS and ONC. As I mentioned, they anticipate the NPRM by the end of this calendar year and their final rule by the middle of next year.

With that I want to turn it over for your overarching comments and questions, and in particular things that we've indicated would be very helpful guidance from the HIT Standards Committee on some of these standards that either exist or would need to be put in place.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, Paul and George for a thoughtful and provocative set of comments. Before we get into discussion, let me just turn to Josh Seidman and ask if there's anything you want to add at this juncture.

Josh Seidman – ONC
No, I'm fine. I'd be happy to ... questions.

Jonathan Perlin – Hospital Corporation of America – CMO & President
That was really a terrific and thoughtful summary of so much of the activity, and as we contemplate our conversation I ask that you do that through the lens of the standards that would support this. I know that we could recapitulate many of the policy items, and the policy items are certainly related to the standards, but let's, in fairness, use it as our lens to the issues that were brought forward. I know that as I think about our own journey in my organization, there's a lot of wisdom in the approach that's taken, and I'm going to ... to ask for dialogue, a number of cards going up here, and if members on the phone want to weigh in, please indicate so as well. John, do you want to weigh –

Walter Suarez – Kaiser Permanente
Hi, Jonathan. This is Walter Suarez. I'd like to raise your card.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, your card is in the queue. I will call you –

John Halamka – Harvard Medical School – Chief Information Officer
If possible, I'd like to raise, as I went through every one of your recommendations I tried to highlight some standards gaps, and so just briefly to mention some of these, so for example on the expanded demographics code sets the IOM 2009 report that you referred to suggests that there are 540 additional granular categories that are represented in CDC and HL7 code sets. So I wonder, Jamie, for example, as the keeper of code sets, that if it is a vocabulary taskforce assignment, because it's quite well specified in the report what this additional set of code sets would be and so to define what its availability in the CDC or HL7. And then, for example, you asked that smoking status now be expanded from the CDC code sets 1-9 to include secondhand smoke, it's another code set issue. One wonders if that's something we assign there. You note that LOINC should be used as the vocabulary for structured labs, so Jamie and I were chatting last evening about well, don't forget that SNOMED is also an appropriate vocabulary for organisms and microbiology, and so we just should also reflect on that.

Let's see, EMAR, now, this may be a somewhat lengthier question so I'll just tag this, but I'm not quite certain we've defined what an EMAR is. Is it bedside medication verification, ensuring we have positive patient ID and standards for bar coding of every medication and every patient and every caregiver. Or is it something else, which is to say it's provider order entry with an acknowledgment by the person delivering the medication that the medication was given. The definition of EMAR can imply many standards dependent on the workflow. Family history, that was highlighted as something that we have, a number of us worked on family history standards in the past, and it's probably a power team to look at all the possibilities there. And longitudinal care plan was noted as something to be merged into the summary and care plan, but I'm not quite certain that standards, other than conceivably free text, would be something that we would use for that. Then finally reportable cancer conditions question, there is the IAG cancer reporting implementation guide and there are other standards. What's in use today, I don't know.

Then finally on the whole security and privacy slide, one of the things that's probably interesting for the committee to review is the OIG's report, issued on Tuesday, which actually criticized some of the work that actually we have done, which is interesting to read about, and OIG report reflecting on maybe we had not, in making some of our recommendations, gone far enough to go beyond technology controls and talk about some business process controls and other things. Again, I don't think it's anyone's fault or any committee's fault, but it just suggests that if you create a wonderful technology fortress and then people use it in unwise manners, that you have not achieved end-to-end security. So in response to the OIG

report I just wonder if there's something on this last slide from a Meaningful Use Stage 2 perspective that should also be included. Those are some high level comments.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Which we'll address in the next few minutes. That is a formidable list. It tees up the attention that we're going to have to provide this summer in the "summer camp" activities. But that's a terrific list. I've also been thinking about, John, the ecosystem that's implied in terms of transmission of information and understand where we want to end up. But like I said, it's an environment in evolution for patients to be ready to receive some electronically transmitted health information implies, not just an eligible provider and hospital evolution, but an evolution that's really a broader social uptick that fosters this degree of interoperability.

I want to make sure, Judy, if we can keep a working list of some of these issues, because we'll thread them back through the summer camp activities. Today, this part of the discussion may be really less directed toward resolution of these issues than teeing up really a sequence of activities, because I think there really will require a great deal of additional thought. So let's go around clockwise. Let's start with Jim Walker.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Thank you, John. I want to add to John's list. On the 20% of hospital discharge medication orders transmitted electronically, we were prepared to turn that on six months or so ago and decided not to because apparently almost all pharmacy systems are unable to receive an electronic cancellation of an order, and since discharge medications are frequently in flux and not inappropriately we didn't think it was safe to start sending electronic discharge medication orders until pharmacy systems were able to receive cancellations.

The next one is on the next slide, and it also comes from our experience. We had a very successful experiment with putting electronic formulary information into our order entry system, an enormous value for patients who get therapeutically equivalent and a whole lot cheaper meds because the doc is reminded of those options in the moment. We were unable to continue that because we could not afford the cost of hand entering just one formulary and so it seems to me that a rational approach would be to say that formulary owners are required to provide the formularies in standard electronic form prior to providers being required to implement them in their EHRs.

The next one is also on that slide, small practices, and I assume small hospitals, have little leverage with some lab systems, and in Farzad's case I think only 38% of those very well set up practices received electronic lab results. So I think there again we need to make sure that the ecosystem makes a requirement rational, and obviously what I think we should do is not deep-six the requirement but make sure that labs are required also. One of the interesting aspects of that would be that if hospital labs are required to transmit LOINC lab results and commercial labs aren't, it could put hospital labs in a better competitive position. I'm not sure how that would work out.

On family history, I want to encourage us to think carefully about what we mean by family history. There are elements of the family history that are highly actionable that you can use to calculate the likelihood that a person's chest pain is due to coronary disease, that you can use to tell a woman what her risk of BRCA1 and BRCA2 are and counsel about further actions, and all of the so-called standard family histories, including the Surgeon General's, are composed of data elements that are of no actionable use in clinical practice. So I think one of the standards for family history is that whatever elements we standardize actually have some clinical application ideally in a clinical prediction rule, but there could be other ways that those are actionable.

Then finally, on the public health requirement, slide 10, again, the ecosystem would be rational if we said the public health agency, at least CDC, over whom we have some persuasive at least relationship, that the public health agency should be responsible for creating a standard template or specification. So that you can imagine in the case of anthrax CDC could have said these are the three questions to ask, and if you entered any one of them as yes, stick them in the ICU and answer to all of them as no, then send

them home and send us the data. Failing that kind of appropriate specification, it makes it unlikely, particularly that smaller organizations would be able to respond in any useful way.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Jim. Very thoughtful and provocative comments, and I think a great demonstration of how those comments might associate with certain of our workgroups this summer for consideration and also the ... Policy Committee. Very helpful. Cris Ross?

Cris Ross – LabHub – CIO
I have questions about two requirements related to providing patients with electronic copies of health information and the capability to exchange key clinical information between providers. The Stage 1 rule of providing more than 50% of patients with electronic copy of health information, I see why that's dropped and there's additional granularity that has been added that may be more powerful. But by comparison the Stage 1 Meaningful Use requirement to exchange clinical information to perform at least one test was a pretty low bar to begin with, and it appears to me as though the bar is still not high. If you look at the comparison of providing patients with data and colleagues exchanging data, it seems as though we've set a much higher bar with respect to data to patients, which I think is fine. But it seems as though exchange of data between providers remains a pretty low bar, and especially since I think most systems would tend to use the same infrastructure to accomplish the same goals, I'm just sort of curious about the connection of that.

And others may disagree, but I look at, for instance, around in the patient requirement we list, for example, in Stage 3 provide a mechanism for patient entered data, but there's no equivalent for our recommendation of Stage 3 provide a mechanism for colleague provided data to be included within a record and that we're providing the ability to download and view relevant information relatively quickly, and at the same time there aren't requirements here that a consulting provider be able to query and receive that data at the same time. I don't know if that's intentional or not, but it seems as though we have raised the bar on patient communication, which in general is good, but haven't raised it from colleague to colleague communication.

Jonathan Perlin – Hospital Corporation of America – CMO & President
That's a terrific set and may be ones that we want Paul and George to speak to. One other thought with that is that beyond this transition consideration of Stage 2 there's also the dialogue going on about Direct and NW-HIN and how the interoperability ecosystem evolves, what interchanges might occur using what supports and by whom. I think your articulation was certainly very familiar. In our organization we contemplate how whatever structure we use for the clinician exchange of information ... sense, why would we want to set up a separate architecture for other interactions, how is this done economically and how do we also contemplate our standards as they go to exchange capacity. John, I think you want to comment on this.

John Halamka – Harvard Medical School – Chief Information Officer
Well, maybe you want to incorporate this into the certification rule, in that Dixie is going to be presenting today the notion of entity level and individual level provider directories and wouldn't we want that colleague to colleague exchange to use an entity level provider directory standard. And so hence that would be a certified function in an EHR to accomplish this, so in fact products may drive the better colleague to colleague exchange.

M
If I can just follow up briefly. I look forward to what Dixie's going to report in our Summer of Fun, but I think one of the things that many of us have noted is that there's a mismatch between some of the container and vocabulary standards in the transport standards and that the two are not in conflict, but they're also not glued together in a sensible way that people know what the road map is. So I'd point at, John, your comment about Direct, for example, is great. The Direct protocols as currently understood are intended to allow addressing of a provider or of a patient on an equal footing. So I think if people are using that protocol they are going to use that transport and that mechanism to communicate with both,

that in practice they may end up using different kinds of standards. In any case, it just feels as though perhaps we can ... more congruence on that issue.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I appreciate that. Let's take that as a thread that we connect, and we'll look forward to Dixie's comments. Before we go back to Paul and George, let's get our work list here, and I want to make sure that we also, working with our colleagues on the phone, I know Walter Suarez we'll go to first, that Wes Rishel also has his electronic card up, so let's go to Walter for a moment.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
Also, Jonathan, it's John Derr, I've got my card up as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, we'll cycle back, so, Walter?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
And David McCallie as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
All right.

Walter Suarez – Kaiser Permanente
This is Walter. Mine will be just two very brief, quick questions. The first one is conceptually about the menu to core, and I wanted to just primarily confirm that the approach be recommended by the Meaningful Use Workgroup is to, number one, move every measure that in Stage 1 was menu to core. And then number two, that there would not be menu measures in Stage 2, the new measures all will be core. Is that a right assessment?

Jonathan Perlin – Hospital Corporation of America – CMO & President
George, do you want to comment, or Josh? I thought I understood the philosophy of trying to move those things to core there would ultimately be a CMS call ... a couple of things and many with the general philosophy was to move them back. Is that, Josh, the synthesis?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
This is George. Yes. CMS stated that their direction was to move what's currently menu to core and we followed that, but we believe that CMS will have to make some decisions based on current adoption, current being a year from now or sometime, six months from now, adoption, and menu is one of the levers that CMS has ... and so we respect that. So what we're putting forward is if things are going well, all this could be moved to core, although we did mention too specifically that we would have put in menu if we had that construct. Walter, I think you basically described it correctly.

Walter Suarez – Kaiser Permanente
Yes, and so the second point really all the new measures being recommended, they're all seen as recommended as core.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
At this point in time.

Walter Suarez – Kaiser Permanente
Yes. Okay, great. Then the second quick question is a little more of a policy question around timing options. It's just like the recommended timing option will be the concept of delaying the transition from

Stage 1 to Stage 2 by one year. There have been some questions out there about whether that is consistent with the HITECH law itself or whether there are some law concerns around the ability to do a full one year delay, or whether there are no concerns basically, that in reality the law did not set up this staging and so the ability of using rule making to do the staging and then modify the staging as it looks like it's going to be recommended will be consistent with the law.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
There's nothing in the law that prohibits the change in staging. Staging is something that's up to HHS.

Josh Seidman – ONC
This is Josh. I think that the thing that the law does prohibit is on the Medicare side there can't be a skipping of a year. So it is for that one group, which is the point of the slide, this slide here, with that for those who start in 2011 if Stage 2 is delayed a year that those providers would have a payment year in 2013 that would be the same as what they had done for 2011 and 2012. So that, I think, also puts into the context some of these questions about the menu and the core, that one of the things that the Meaningful Use Workgroup did was to try to have the conversation about both new objectives and the decisions about menu versus core in the context of the broader national quality strategy, the proposed ACO rule, and the broader goals around the ... delivery system reforms and in doing that identified the things that really were on the critical pathway to delivery system reforms to the goals of the national quality strategy and try to put those things in place. If the timing option three was used, what would that mean in 2014, what are the things that they would think delivery systems would need to be able to do around care coordination and patient centered care, etc.

John Halamka – Harvard Medical School – Chief Information Officer
One wonders, I mean given that you look at everything that's been presented today, and some are just changes in thresholds and some are new standards and new functionalities, if you said, you know, for 2013 we'll split Stage 2 into two pieces, 2A, which we will not change the timing of and it will incorporate just those exact Stage 1 criteria with simply thresholds that are a little higher. Then 2B, which has a year delay for the vendor community and the standards community and the implementation and the doctors and everybody to now get on board with new functionality, or is that so complicated you don't want to go there?

Jonathan Perlin – Hospital Corporation of America – CMO & President
... this may be, I want to remind the group that remember our perspective is to frame the standards. I know we all feel passionately, both in our personal lives and at a policy level, but let's make sure that we get the frame of the standards in this. Elizabeth?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
What Dr. Halamka just suggested is something that we had considered and we were calling it a Stage 1 prime. So it's something in between Stage 2 and Stage 1. Part of the issue we are having is that providers are very confused about meaningful use overall, we're getting thousands and thousands of questions because they're so confused, and so our hesitation is that we don't want to confuse them even further by creating an interim step between Stage 1 and Stage 2. But that said, we're really going to be looking very closely at the data that we receive, and so far I will tell you, quite honestly, we have very little data because people are just not coming in and attesting at the levels that we were hoping that they would. So when we make our proposal for Stage 2 it will be a wide net so that we will be able to ratchet back if we need to in the final rule based on comments we receive and based on actual data to see where people are having difficulties and to see what is most appropriate in moving forward.

Jonathan Perlin – Hospital Corporation of America – CMO & President
That's very helpful. I appreciate, John, you're coming back to the work of the standards that is implied by that, so thanks for that. I know that there are a lot of card ... so let's keep our comments focused. Let's go to Wes next. Wes, are you there?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, I am. Thanks. I have one comment building on Jim Walker. Recognizing the difficulty that we have under this legislation imposing standards on other players in the healthcare arena besides providers, particularly we've already talked about labs, but in this case we're talking about payers with respect to formularies, I was going to suggest an alternative formulation, to Jim's proposal, which is to say that the meaningful use requirements on healthcare providers, the use formularies, is only applicable where a payer has voluntarily certified that they transmit formulary information according to a standard. So there's no obligation on payers to certify, but there's a big possibility of a return on investment in terms of subscribing that better matches the formulary if they do.

My other question really is about the Stage 2 timing option slide and wondering how it would look if 2015 were also shown in the chart. As I recall previous discussions, everybody jumps to Stage 3 in 2015. Is that correct? I think an understanding of that is important in terms of timing for vendors for Stage 3, are we going to get into the same bind we're in already with Stage 2. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
There's a lot of body language that's also wondering about this. Elizabeth looks ready to volunteer to answer.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
We had originally, in the NPRM, proposed what the stages would be for 2015, and then we left it blank in the final rule. So there's no proposal what the stages would be. The difficulty we have is that 2015 is the year that the penalties kick in, and so we're trying to figure out what year to base that. We're planning to put something in the NPRM about how the penalties would be levied and what year of data we would be looking at.

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... on the Medicare side, the last year that incentives can be paid is 2016, so you can think about different options for how to do 2015 and 2016, knowing that 2016 is the last year that incentives could be paid on the Medicare side. Obviously the penalties would be going on, as far as we know, for the foreseeable future.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
... through 2021.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
This is Wes. I'd just like to suggest that before we get to the NPRM for Stage 2 we have extrapolated this table out to Stage 3 and have a clear view of whether we're just pushing a ..., kicking that ... down the street or whether we're actually changing it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. Just to connect that back to the standards piece, I think that part of our obligation is to be working with ONC and the Policy Committee to make sure that the standards that are articulated are accretive and help to thread the needle over the near, mid and longer term, looking at ... the end of the incentives, the beginning of penalties, and whatever standards are upheld by regulation at that time as a continuous trajectory. So I want to ... our standards work. On this point let's take one other comment, Jim Walker, and then we'll continue with the roundtable.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Just very quickly, I think Wes' formulation is vastly superior to mine for the work list.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you –

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

... formulary, Jim.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, let's go to Marc Overhage.
Marc Overhage – Regenstrief – Director
I just want to follow up on the formulary discussion, and Cris and others in the room may want to comment a bit. So this isn't a standards problem, right, there is a pretty good standard for formularies that lots of payers support and use and it actually works pretty much.

The second observation, and this gets back a little bit to the business process things, be careful what you wish for. The formularies, as they are currently constituted, are incredibly large, incredibly unwieldy, and incredibly expensive to maintain, not for the payers to maintain so much, but for the EMR vendor to maintain and integrate into the systems in a meaningful way. And we have a number of business process issues about updating those formularies and synchronization of the various components and so on as they get down, whether you can grab pieces of the formulary that are out of sync, so I think this maybe is less of a standards question, and it gets back a little bit, as it so often is, to motivations and alignment. But I actually would push for it to become a standards question since I think the standard we have is usable, because people are clearly using it, but at a pretty significant cost and expense and maybe an evolution of that standard might be in order.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. Let's go to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Hi, Jamie Ferguson here. There are a lot of big, weighty policy issues being considered and I have a narrow little standards issue that I want to bring up, that I think is nonetheless important for the actual use of the EMR, and it has to do with problem lists. Obviously we're looking at an increase of the requirements for problem list for Stage 2. When we look in the vocabulary taskforce, and this will be part of our later conversation, when we look at the available subsets of vocabularies for problem lists that could be used in certification we see two flavors, if you will. One is, so there's the most recent release from NLM, I think, is a download of the top 2,500 SNOMED problems, which shows exclusively findings and disorders of actual problems in SNOMED being listed there, the most frequently occurring 2,500 problems.

When we look at other problem list subsets that are generally larger subsets that are based on the experience of the way EMRs are used in the wild, where the problem list in fact comprises in some cases a majority, so there's one downloadable that's about 6,000 terms, where a majority of the problem list is actually procedures, therapies, medications, and frankly things other than problems, so I think the question that we have then in this for the Policy Committee working group is what are you looking for in problem lists? Is it actually a problem list that's problems, or is it problem list as a catch-all?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Actually, I'd love to get a response from Paul and George on that, if possible.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think, Jamie, you point out that although problems were defined initially in practice, people apply the term "problems" to various things. In fact, we would appreciate the Standards Committee's help on that definition. The reasons we're moving, Stage 2, actually we didn't do anything with the problems meds and allergies. We're hoping in Stage 3 to move towards a concept called ... and that is something we're going to struggle with. We're thinking that between now and Stage 3 a lot of these tools, whether it's clinical decision support or other kinds of reminders, are ways that you leverage the problem list, will prove to the clinicians that this is a very useful thing to maintain to date and will be self-reinforcing.

But right now we feel like it's sort of a boot strapping time. In fact, we do have to come up with two concepts, a definition of what's an appropriate thing to be on the problem list, and two, how would we define up to date. The Standards Committee's input on that would be very, very helpful. So for the end user, so for the clinicians what would make the most sense? Is it a catch-all of everything? A lot of us consider this notion of active problem lists, things that should be top of mind when you're faced with a patient no matter what kind of decisions you're making and trying to distinguish that from "past medical" and "past surgical" histories. So there is that you know it when you see it, but it would be helpful to nail down a definition for that.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
I'll just say that in the stakeholder input that we've received so far we see different views that different providers have, and some use the problem list, as I said, basically just for findings and disorders and have a different place for documenting procedures, and others just say well, this is the first thing that comes up on the front page of the EMR so we're going to throw everything in there. I'm not sure, frankly, that the Standards Committee is the right place to tease out that issue in terms of the intended use of the EMR.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think that's a critical issue in the interface, Paul and George, is that the intent really will help in terms of the standards definition as will the trajectory and as this discussion ensued, it would take us potentially to different ways of contemplating an approach to standards.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's fair, and just sort of an off-the-cuff reaction, if more the ... which is finding some disorders, we do not want this to be a place to put things just because our systems are designed for that to be the only thing that's most successful, so that would be an incorrect approach. Hopefully we can, through the certification process, make it easy for people to access the information they need and not have to resort to a coping mechanism where you ... problem list with all the things that you want to make easily accessible. I think in a sense of direction and trajectory we're headed toward the original definition of a problem.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. That's very helpful. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Are there any other comments on this particular issue, problem list?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
This is Jim. I just propose an operational definition that things that belong on a problem list are things that might require an intervention, whether that's monitoring, testing, treatment, discussion. I think part of the problem is everyone has some kind of operational definition in their heads and I think we can get something that would represent most of it, but problem lists, while everyone knows what it means, it's one of those things that doesn't mean what it says and everybody translates it to something else. It's like things that go on an allergy list are things that are relative contraindications to using the drug, usually in actual practice, different things in an allergy, and so we have this problem where we have names for buckets that don't actually represent what go in them. I agree with Paul, meds and procedures, just because you have a badly designed EHR, that's a whole different question.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David.

Jonathan Perlin – Hospital Corporation of America – CMO & President
David, on that point?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

On the problem list point, I would agree with Paul Tang's general sentiment. But I would also caution that there may be things that we should be capturing on the problem list that aren't strictly speaking problems but might represent intermediate states of reasoning about a patient that are important to pass on that may be one step prior to the formation of a problem.

Second, is the fact that the problem list hasn't been well maintained in general, the fact that we had to turn it into a measure, suggests that we really haven't figured out the right utility for the problem list and that the challenge, I think, to the EHR vendors is to figure out how to make the problem list more useful and therefore more valuable to keep up to date.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific thread of discussion, and very helpful in framing some future discussion and obviously the standards work that will follow. Let's go to Kevin Hutchinson.

Kevin Hutchinson – Prematics, Inc. – CEO
I have three quick comments, one of which I'd like to hear George and Paul's response on. Initially, as we get into Stage 2 as a committee we're going to have to get guidance, either from ONC or as a committee, to come up with our own on this balance between the work of the standards versus the work of implementation challenges, because I would agree with the comments that Jim has made around the challenges the pharmacy's had with implementing cancel and change prescriptions, that's an implementation issue as we look at discharge medications it's a workflow problem and how much of that do we go into with respect to workflow versus establishing a standard, it's hard to separate the two, quite frankly, because it's come up with a standard that's difficult to implement or brings challenges to the workflow and we haven't really come full cycle with what we're trying to do as an industry and as a committee.

The second comment to make is as we get more and more into Stage 2 and I look at a lot of the detailed data that we're going to start implementing within the EHRs and within the use, just to revisit how we intend to audit or ensure compliance with this. I know a lot of this is attesting to the fact that it's being done, but it seems like we're getting more and more granular in our data, in our percentages of what's being done and how we're going to ensure compliance on a physician by physician basis.

The last item is one I'd like to hear just comments back on. I notice that we're adding in certain elements, for example, secondhand smoke use, and I wonder from the Policy Committee perspective, and this will help give guidance to us as we think about the work around standards, is there a particular goal that we're establishing at the Policy Committee level around quality improvement, around particular conditions, diabetes, cancer, obesity? Are we establishing a goal in which we want to reduce a certain condition to the use of meaningful use so that we know how to drive those quality improvements in those standards into the process, or are we just looking at overarching elements that affect or impact care? I'm not giving judgment either way. I'm just trying to understand, as we establish the standards and we go into the quality improvement phase of this next, especially as it leads into Stage 2 and 3, if there's targeted conditions that we're looking at.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
From an auditing point that was something that came up at the Meaningful Use Workgroup and our CMS colleagues are going to be providing a brief presentation to the Meaningful Use Workgroup in about two weeks on a series of issues that have come up and so forth, and I'm sure this committee would like them to do a presentation, and I'm sure they would be happy to oblige.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
This is George. On the first question, our goal in effect is to change the workflow in the country's healthcare. So to the degree we set standards, we are trying to make things better. That's why we're here. On the other hand, we can't overstep our bounds and we have to see where things fit into current workflow. Taking discharge medications as an example, I don't know if Jim was talking about where you write your discharge orders and then the patient doesn't go home so they get canceled and you don't – as opposed to once the patient's out the door it seems you don't usually change the discharge medications

after that minute. So the workflow change would be that you'd enter the discharge orders, but not execute them to go out until the patient's going out the door and the EHR might support that. It might actually reduce confusion and improve efficiency if we could implement such a thing. So if we could push forward a change in workflow that improves, and this wasn't on our minds when we wrote that objective, ..., but if we can do something to improve the workflow, that's good. But we can't go against the workflow and cause problems and potential medical errors.

Kevin Hutchinson – Prematics, Inc. – CEO
Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's continue our enumeration of some of the broader issues. We've got a couple of folks on line that are trying to weigh in. John Derr?

John Derr – Golden Living LLC – Chief Technology Strategic Officer
Yes, thank you very much. Three ... on the percentages and that it only lists discharges for patients and mainly assuming they go home. In tomorrow's world, as in today, a lot of people go to either home care or to skilled nursing facilities for rehabilitation and also in trying to solve the re-hospitalization thing. So I volunteer to take some of those places ... and then add some comments to them, because I think once we get into Stage 2 people will say, well, can I count a discharge to a SNF or a home care agency as part of my making the goals.

The second comment, the average length of stay in a skilled nursing facility is only 24 days because they're turning a lot into being a rehab type of sub-acute facility, and under the care coordination we tend to use the term "long term care" when it's not really long term anymore, it's more of a rehab type of thing. Also, in legislation LTC usually is synonymous with SNFs, when really 40% to 60% of the discharge, depending what study you look at, either go to a SNF or to a home care type of agency. And in real life we're looking very strongly at finding a lower cost but high quality provider rather than the hospital, especially for short-term rehab, and I think we should probably recommend not using the term "LTC" anymore, but find some other term or rehab facility.

On the timeline, we've taken into account that vendors have to do work, well, there's a whole new set of vendors, except for our friends at McKesson and at Cerner there's another set of vendors and if we don't take them into consideration at this point in time once we get to Stage 2 or Stage 3 and we have to transfer somebody to one of these long term post-acute care providers their vendors will not be able to accept the information and also will not be able to send the information back to the hospital in case there is a re-hospitalization. I volunteer to help out on any of these aspects if the committee wants to add those. Again, I know we're not in legislation but we are working very diligently to have interconnectivity and interoperability no matter what the incentive program is because we know it's the best thing for our patients.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I'd just remind that we're going to try to be as vendor agnostic as possible in the discussion. With that said, I think the broader points, John, that I'm going to pull out of your comments are, one, the general counsel on rehabilitation and post-acute environment are very well taken, your willingness to help the second is really the things that Jim Walker and Wes brought up about making sure that the use cases accommodate the real world, not an idealized world where the use case, or the standard solution may break down. I think that thread is there and it really needs to be informed by the richness of probably not every last exception, but those exceptions that are reasonable and recurrent. So that's much appreciated. Let's go to Carol Diamond.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Thank you. I have just three comments. One is to pick up on the thread that John ended on, which is the issue of privacy and security and the flag in the OIG report. One thing I would say is that when we as a committee made our security standards recommendations at the very early part of Stage 1 the Policy Committee had not yet formed the Tiger Team, and the policy recommendations that have ensued were

not yet available. I think part of that is just the artifact of this process and the balkanization of the two committees, but in many ways the Tiger Team was the place where that got resolved. So I do think we need to flag it in Meaningful Use because while there will be new security requirements from a technical standpoint, the policy practices that have emerged from the Tiger Team need to be married with those and we need to take those into account as a full package. I just want to flag them, because it's an artifact of the way the committees have been constructed and the timeline, but I think we have to bring it back together.

The second point I wanted to make was on the download capability. We tend to talk a lot here about content standards and vocabularies and transport standards, but I think in some ways our role is also to figure out how to make implementation easy. One way to make implementation easy on the part of providers is to start to make some of these capabilities a capability of qualified IT, in other words, not have the provider figure out how to get a capability that's Stage 2, but say, look, this is just an inherent requirement, qualified IT, and I think download capability clearly fits that, along with automated counts of its use. In other words, computers do that stuff well, better than people, so I think those are places where we could put recommendations forward that are more in the capability and technical requirements category than they are in the standards. But I don't want us to lose our ability to use some of those levers here.

Then the third point I wanted to make, I totally understand the rationale for dropping the electronic copy. I think the slide cites HIPAA. I probably would suggest they cite HITECH, which is really where the legal electronic copy right came, HIPAA is a copy, and HITECH said you have a right to request it in electronic format. So I totally agree with dropping, because it is taken up in other elements of the Stage 2 requirements, but one thing I would encourage is that we be explicit about the fact that the download capability is a way to fulfill that. In other words, sometimes things get balkanized between what is meaningful use and what is separate legal requirements, and I know we don't want to get into some of those legal requirements specifically in the Stage 2 recommendations, but I do think that there's value in being explicit, that the view and download capability can fulfill that objective. It should presumably also fulfill the objectives of sharing care summaries or whatever information needs to be shared with the patient, and that is a conduit through which this can happen, especially if we look at it as a capability and not as a standards problem. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I appreciate the threads on the privacy and security, the issue of the automation of ... IT and the communication of record. Doug Fridsma, I want to weigh in on your comments.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I just want to make a real quick comment, which is part of the charge of this committee is not just standards but certification criteria. So we have to make sure that when we do the interim final rule, we didn't actually do all of those pieces, so we need to make sure that this committee comes out and addresses not only standards but if there's something that doesn't require a standard but needs to have a criteria for testing that that functionality exists, we need to make sure that we spend time doing that as well.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
That's exactly why I made the comment I made, because I think sometimes we lose sight of that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. Okay, a good continuing thread to Dixie, particularly if there's anything you want to comment on the security aspect.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, actually Carol talked about the two topics that I wanted to raise ... is the OIG. And I would agree that the standards that we put forward certainly didn't address operations, and I would go further to say that the next ones we put forward aren't going to address operations either because that's really a Policy Committee responsibility. Carol and I and Wes and David are all on that Tiger Team and I believe we

have made considerable steps toward tightening the policy in privacy and security that will ultimately translate into improved operations.

The second topic is the second topic that Carol addressed, although I disagree with her conclusion. The decision to drop the capability to download an electronic copy of the patient's record, she's right that HITECH is where that requirement comes about. HIPAA requires that you provide a copy of the electronic record to the patient and HITECH says it has to be electronic and that you have to provide the capability to give it to them electronically. HITECH goes one step further and says that if the patient requests that you provide that electronic copy to a third party, such as a PHR, that the provider must do that. This is where I believe that the meaningful use measure needs to be retained because that should be done with standards. The capability to download that to send that electronic copy to a third party, such as a PHR or another provider, should be done in a standard way and I would suggest a request that you reconsider dropping that and make it instead making the measure the capability to provide an electronic copy to a third party such as a PHR in a standard format. I would also point out that this is consistent with recommendations from the PCAST taskforce as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think Carol and John both wanted to come back on this one thread. Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes, I just wanted to say that I don't think download precludes the upload. In other words, when we participated with the VA and CMS and DoD who provided download capability, there were a whole host of vendors who had the capability to upload that data into their own apps and services and there were a whole host of innovators who developed new apps to do that. So I don't think it precludes the concern that you have, and in fact I think it will make it easier because it will be one set of functionalities and the expectation for that capability will be that a vendor who is writing an app to upload that information has a common expectation of what's going to be provided and how it will be provided, as opposed to saying there's a legal requirement that you have to fulfill this electronic copy to the patient and providing it to any PHR, which leaves I think a lot of questions on the table for anyone who wants to really fulfill that.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
This is Wes. I'd like to put my card up.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
And David as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
David, I've got you in queue. Let's go to John Halamka.

John Halamka – Harvard Medical School – Chief Information Officer
Just to amplify this thread, here's an example to the committee, which is, if you recall, Dixie, back in the very early recommendations we said REST and SOAP would be a wonderful transport standard, choose which of the two you wish. Well, it turned out that in the final rule that there was actually no transport standard provided, but neither was there true certification or testing criteria for the exchange of information. Basically what happened was you had a certified system capable of emitting a content and vocabulary standard, but then there was no specificity or testing as to how actually two parties would exchange the information. So, Elizabeth wrote an extraordinarily elegant e-mail yesterday saying, oh, actually this is what we meant, which is the electronic exchange of information should be S/MIME, SMTP, SSTP, REST, SOAP, we just didn't tell you that that was the list you had to choose from. So, no, physical media exchange like a thumb drive and a DVD, does not qualify. Well, I've written, Micky's written, we've all written caustic blogs about, gee, you know, hey, John, we get to keep meaningful use, only to now know that the certification criteria we should have all specified and said we're not going to tell you the standard, but here is really what we mean. So I think it's an important question.

Jonathan Perlin – Hospital Corporation of America – CMO & President

On this topic, let's take a couple of brief comments. Wes, you wanted to weigh in on this topic, and, David, I know you were in the queue and we'll go to you after that. And we will take Janet Corrigan for the last word on this terrific and provocative discussion. Wes, your comment on this thread?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I just wanted to comment a little bit about Blue Button. I think it was a very interesting demonstration of what can be done in a novel way and a way of getting to a common approach across a lot of implementations from the point of view of the user, the patient, which is very helpful. My current understanding, however, is that there are no real standards for the content that is downloaded using Blue Button and while it's easy to see vendors customizing their pickups for big providers like VA and DoD, it probably creates an unequal advantage in the marketplace for big providers if there aren't standards so that the people who would make secondary use of the data can pick up data from more normal size providers with equal facility.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Wes. Carol, be brief on this.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes, I would just say that in the recommendations that we made for download capability the standard that we held hard on was that it's human readable, that ultimately this capability is to serve the patient. We also said that if a provider of the data can provide it in another standard as required by meaningful use, whether that's CCR or CCD, that they should do so, but that human readable is still a requirement. The only other thing I would say is that you are correct to say, Wes, that it's not that no standard was available, ... file basically for the download capability, which by the way has been downloaded now, someone can correct me from the VA, over 200,000 times. But it also allowed for new vendors to enter the marketplace who had no familiarity with health standards or CCR or CCD like, for instance, Adobe, to develop novel apps that they might not otherwise have developed had they not been in the health sector and familiar with the health standards and health construct.

I think it's a valid point to raise. I think as we get more standards requirements in meaningful use and of qualified IT, it has to get itself sorted out, because, as someone else pointed out, the sharing of information with the patient versus with another provider ultimately is going to fly over the same wires and use the same infrastructure, but the key requirement now to make it useful to the patient in our view was to assure that it's human readable.

Jonathan Perlin – Hospital Corporation of America – CMO & President
And I think the broad counsel that's coming forward is ... the use case and the practicability, that is how do the standards help inform the implementation in the real world and the foreseeable future, the time frame here. I know there are a number of cards that have gone up at this point, and, Jim, you've had your card up for a while. Is there a very brief comment from you, Jamie, or Cris on this thread before we go to the next?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
..., no.

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.... very brief on this thread, and that is, let's not forget about privacy and security, and so downloading in clear text really I think is not appropriate given the current focus on privacy and security, that some sort of encryption or other method for protection should be required, that clear text doesn't do it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
That's terrific. So there are a number of attributes that we need to keep in the list as we contemplate standards. Cris?

Cris Ross – LabHub – CIO

Very quickly, I would dissent with the notion that we're likely to send communications to patients and communications to collaborating physicians over the same wires or using the same protocols. I think the way we would format and present human readable information for a patient is vastly different from the way we would format and structure information we're passing to a colleague that we would expect would be able to upload it intelligently into their electronic medical record systems.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. I'd like to weigh in on that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes, go, David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Just a couple of things to tie some of these strings together. I think one is just a plug for the direct protocol, which I think could fulfill a number of the use cases that are put forward here in Stage 2 proposals. As Cris Ross elucidated earlier, sending a copy of electronic information regardless of the format, whether highly structured or just human readable, to another provider or to the patient using Direct is certainly feasible and within scope of how we've designed those protocols, to the point where I would suggest that a certification criteria that we should consider for Stage 2 would be the ability to interact over Direct. I think that is a common pathway that would satisfy, I think, all of the requirements under Stage 2. I do also endorse the download notion. I think that's an independent way for a consumer to pull their information. So that's my point number two.

Point number three is I think that as we start envisioning multiple ways that a packet of healthcare information moves from sender to receiver, where in some cases it goes direct and in some cases it may go via an intermediant like the patient, that we should make sure that our focus on the provenance of these bits of information includes a digital signature, which is of course not the same as encryption but it could go along with encryption. But a digital signature to make the data tamper-proof, which I think in the long run will increase the value of these intermediant mechanisms for moving the data around. If a patient can deliver data to their provider, perhaps when they move to another city and there's no easy electronic means for that transfer, if they can provide that data in a way that the downstream provider trusts that the data hasn't been forged or tampered with, I think we will overall increase the value of these different mechanisms for interchange. And I'll stop there.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, David. I believe that the last word goes to Janet Corrigan.

Janet Corrigan – National Quality Forum – President & CEO
I'll be quick. First, I'll applaud the Policy Committee for putting in the longitudinal care plan. I think it's really, really important, for a couple of reasons. It really can be the vehicle for collecting all of that patient reported outcome data, the health functioning, the health behaviors. But in addition to that, a good care plan usually has goals. So you can begin to move towards measures, a dashboard that clinicians and patients can have that would actually look at how much you achieved your goal in terms of weight loss or whatever. So it really captures a lot of important things.

I do want to flag, though, for some of our government colleagues, that there's a set of parallel activities going on in different parts of the federal government that all relate to this. One of them is under AHCA there was a requirement to cover an annual wellness visit and as a part of that it's supposed to include a wellness plan. Well, a wellness plan is just all sort of the same thing whether it's a wellness plan, a treatment plan, a care plan, a prevention plan, it's a plan, and they're all the same stuff. The group in CDC that's working on defining the wellness plan, the domains and the data that needs to be collected as part of the wellness plan, I believe they're working collaboratively with CMS to put out some notice of proposed rule-making that I don't know how specific it was just recently pertaining to this aspect of it. But there's major activity there.

The second piece of activity going on is up at NIH, and there was cross-institute activity that was held on May 2nd and 3rd, a two day workshop to define the data elements on behavioral and psychosocial aspects,

the core data elements that need to be collected on every patient. And I think that activity is building out a wealth of work that's been done in the research community on health functioning instruments and others.

Then the third activity of course is the notice of proposed rule-making on the accountable care organization that does include either a general requirement or a proposed requirement for development of a care plan, which may well get more specific as the comments come in on that.

So I think we have a big opportunity here to actually pull these threads together because some of them have hard and fast deadlines for implementing these plans as a part of other initiatives, if they can be brought together there would be a lot of synergy there. But the second thing is if we don't get out in front of this in terms of defining standardized components of the longitudinal care plan, and being a bit more specific here, I think we're going to have a lot of frustrated caregivers on the front line because they've got to move ahead and put those care plans in place. And absent any standards guidance, they're just going to be doing it on their own.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great comment.

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Jonathan Perlin – Hospital Corporation of America – CMO & President
It takes us back to, really the thread that Farzad started us on this morning, which were the improvements in the health system. Josh alluded, as did George and Paul in the presentation to desirable attributes, and I think the ... any messages out of those is there needs to be parsimony, parsimony with the clinical and social intent for better and higher value healthcare, parsimony with other programs, Josh, you mentioned a number. Obviously, CMS has not just the ACO but the value-based purchasing and a number of activities that seek to improve that quality and value, a parsimony technologically that allows an efficient adaptation of outward development evolution of the information systems, a parsimony in terms of facility for implementation, I heard Carol say make it easy or easier. I don't know that easy is going to be the ultimate attribute, but certainly I think if we seek parsimony as the virtue we can make it easier. I see John smiling. I know this has been a parsimonious word that you –

John Halamka – Harvard Medical School – Chief Information Officer
... use that word.

Jonathan Perlin – Hospital Corporation of America – CMO & President
But that an economy of intent, it doesn't mean that we shouldn't be ambitious. Obviously, what we've heard this morning is incredibly ambitious. What I think we're hearing, or at least I'm hearing if I'm processing your input correctly, is that we need to be parsimonious, we need to be economical and efficient in pulling together some of the threads, not only not letting perfection be the enemy to good, but not tripping over ourselves in terms of incompatibilities. Cris, I respect the point that you made, that there may be different frames for transmitting between professional and patient environments. Where I don't think I heard any disagreement was in the systems that are being propelled by virtue of the meaningful use requirements that the capacities that can be built in, as Carol noted, to really need to be able to interface with an evolving ecosystem that can transmit meeting requirements of the different constituencies. Some of that may be ultimately supported to be more or less human readable by different technologies that make it non-bidirectional, that the recipient in this case might be using, but there are some parsimonies that we can support technologically.

We had a good discussion about pharmacy and transitions of care from a number of members, Jim and Wes, and John and Janet, and in all of these use cases where, again, there has to be a symmetry with the real world. Jim, you're itching for a comment, so I know you'll be the first part of the quality ....

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Just very quickly, to add to that, it's our experience that if communications to clinicians aren't human readable in the current environment and anything foreseeable in the next ten years, they also aren't usable, so we just need to keep them in mind also.

Jonathan Perlin – Hospital Corporation of America – CMO & President
The typical scribbles of hieroglyphics prove that point, I think, in the paper-based environment. Let's –

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I have a card up, this is Nancy Orvis. I don't know when I can make a comment, if possible. One of the things that I also noted broadly is all this discussion of care plans, and this is partly to the vocab group, Jamie, we all know a care plan when we see it, but the definition of the expectations of that, if we're going to put out meaningful use criteria about that based upon, simple or easy, we need to at least put out a reference of where we're using the foundation definitions of what a care plan contains or may contain optionally. I bring this up because I'm trying to do this documentation myself on some information exchanges we are trying to do for continuity of care and transitions of care, and there's HIMSS data, there's American Nursing Association definitions, there's all kinds of things, so some of that needs to be part of this if we're going to recommend in this area we need to get those baseline definitions in place, as always.

Secondarily, simultaneously the care plan movement is very big right now and a lot of work going on in the Standards Committee on computable sections of it and dates and so on and so forth. So if there is prioritization needed, we should have a very active discussion between those groups as we talk, because there's a lot of discussion about putting clinical statements in care plans that go all the way to SNOMED CT reference terminology. I do not believe that we're going to be requiring that in Stage 2 as a mandatory, but there are lots of discussions about the ways to clearly document and then retrieve computable pieces of the care plan and due dates and care plans. So perhaps clarification on whether the care plan does ...create sent for a patient, that it contains the expected due by dates for each of the parts of the care plan, I think that is a critical piece to make sure. An active care plan has expected dates for both the caregiver and the patient.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, let us close this conversation, obviously one we're going to come back to a great deal, but lots of great input. I think John and I were just side barring a lot that will feed directly into all of the summer camp activities. I know Doug has been taking copious notes and I may begin to address some of these adding to the to-dos of these groups in the ... this afternoon. With that, let's move to the privacy and security, and let me turn to Dixie and Walter, so we'll get right into that. Many thanks, Paul Tang, George Hripcsak, and Josh Seidman for your terrific leadership of that.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Thank you, guys. Thank you very much.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you all for this very rich input. Please work on the care plan. Thanks, bye.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Gee, I'd like you all to notice this is the earliest in the day I've ever had the honor to present and I owe that to my co-chair, Walter, who is giving a keynote address at our usual late time slot, so thank you, Walter.

Today we're going to present our recommendations for EHR query of provider directories. I'd like to thank the entire workgroup for all their contributions. As any of you who dial into our workgroup meetings know, we have very, very active conversations around these recommendations and requirements, and I really appreciate the support that we get for this workgroup.

The HIT Policy Committee is responsible for initially identifying the need for a consistent approach to cross-organizational provider directories to support the exchange of health information. The Information

Exchange Workgroup of the Policy Committee is a workgroup that this work came out of and fortunately for us Walter Suarez has been chairing the taskforce under that workgroup that's been dealing with provider directory. So we have a very, very tight integration here between what's happening in the Policy Committee in the area of provider directories and what we're doing on the Standards Committee. Last September the Policy Committee and the Information Exchange Workgroup of the Policy Committee held a full day of public testimony around provider directories, and as a result of that testimony they considerably narrowed the focus of their policy work in this area to focus on two things: one is interoperability among existing provider directories; and secondly, interoperability between electronic health records and provider directories and the capability for EHRs to query a national federated enterprise level provider directory. They discovered through that testimony, and the testimonies are available online on the ONC site, that there exist a number of directories already, and so they particularly didn't want to see a rip and replace of all those existing directories, but rather the capabilities to capitalize on what's already there and to make them interoperable.

The central need they identified was the capability to search for and find discoverable information that's essential for enabling the exchange of health information between enterprises. So the focus really isn't changing, it's on exchange of information, it's not on internal LDAP directories, a number of which already exist, and the focus is on directories that actually expose an external interface to allow external query of their information. The initial focus of the Policy Workgroup was on enterprise level provider directories, ELPDs, and they recommended that the content be limited to basic entity information, name, address, human point of contact, externally accessible information exchange services like whether you can exchange using the direct protocols that David mentioned, or whether they're on the NHIN Exchange, or exactly how you can go about getting information to them or information from them.

Then the third area was security credentials, and I'd like to pause at this point and give Walter an opportunity to add anything here that I may have overlooked. Walter?

Walter Suarez – Kaiser Permanente
Yes. Hi, Dixie. I think I'm going to let you continue, as I think you're doing well.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
All right, thank you. We're taking a two-phased approach to developing the recommendations regarding provider directories. You'll recall that at our March meeting we recommended that even though the Policy Committee is separately addressing enterprise level provider directories versus individual level provider directories, that from a standards perspective they really need to be addressed simultaneously, and we came to this group and said we would like to address both enterprise level and individual level standards at the same time. And we were told, yes, that's fine. That makes a lot of sense from a standards perspective. But... ONC said, thank you, Doug, we need some recommendations for Stage 2 Meaningful Use specifically addressing EHR query of enterprise level provider directories, and those are the recommendations we're presenting today, it's EHR query for Stage 2 Meaningful Use.

We're continuing to develop standards recommendations for enterprise level and individual level provider directories, and we're addressing these in concert. This committee has already received from the Policy Committee through ONC the charter to recommend standards for ELPDs, but the Policy Committee did not, until earlier this month, approve the Information Exchange Workgroup's recommendations for ILPDs or individual level provider directories. However, as I mentioned before, because Walter is involved in that work, my workgroup has been able to look at what's coming out of the Policy Committee in advance and we've been looking at ELPDs and ILPDs at the same time. This is just the Policy Committee's diagram of what I just said, the types where standards are needed. There are standards for structuring content of the ELPD, how one submits information to a national registry of ELPDs, and then we have a need for standards for query and response from the EHR to the ELPDs and certification criteria as well. And again, today's focus is on the right side, that blue box to the right, standards for EHRs, standards and certification criteria for EHRs to query an ELPD. And we'll also be presenting our recommendations on standards implementation, specifications, and certification criteria.

Our workgroup received testimony from a number of entities. We've received testimony from both the Direct project and from the Exchange project. We've received testimony from the Veterans Health Administration, from health information exchanges in both Vermont and Massachusetts, New England healthcare Exchange Network, and we've received testimony from three standards development organizations. IHE, Integrating the Healthcare Enterprise, presented to us their healthcare provider directory profile, which the Social Security Administration has implemented and piloted. The X12 provider directory transaction, and the third is HL7 and OMG's collaborative activity to develop a healthcare and community services provider directory set of standards. You'll hear me say this several times but I'll just start right here that the HL7 OMG activity, that set of standards is about a year away and the other two are the only ones that are really completely developed at this point. Marc?

Marc Overhage – Regenstrief – Director
Have either of those been implemented anywhere actively?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The IHE profile has been implemented by the Social Security Administration, but has not been broadly implemented beyond that.

Marc Overhage – Regenstrief – Director
I understand they did a pilot. I don't think it's being used, is it?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Walter, do you know? I think it's being used, but I'm not sure.

Marc Overhage – Regenstrief – Director
They're testing –

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think they're just –

Marc Overhage – Regenstrief – Director
... pilot.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think they're still in the process of testing it, yes.

Walter Suarez – Kaiser Permanente
It is only a pilot. It hasn't been deployed and operational ....

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, and X12 is in the process of updating their provider directory transaction to 5010, but the older version, with ICD-9, is implemented and in use for slightly different purposes, as we'll see. Let's see, there's a need for standards implementation specifications and certification criteria. This is the scope of what I'm presenting today. I've covered that first bullet. So we've really looked at standards and implementation specifications for schema, vocabulary, to populate the fields in the schema, transport standards and query language to query the directory. The certification functionality that's needed is the ability to search for and discover exposed information about entities, or organizations, to search for and discover services that that entity offers, and finally, to search for and discover the entity's security credentials, that is, its digital certificate, and the digital certificate's point of review is what's used to authenticate the two ends of the exchange, the sender and the receiver, and it's also used for digital signatures as well.

We heard testimony from both Direct and Exchange, and this chart summarizes what each of these exchange sets of standards use. To discover entities or to find the address of an organization, the Direct project uses the Internet domain name service, which is what all of us use to translate a www....com into a number. To discover exchange capabilities there's no set standard way to do that. The third is to

discover security credentials. Right now they're primarily using the domain name service, storing the security credential in DNS, and there's some LDAP. LDAP is the Lightweight Directory Access Protocol, that's what most organizations use to query an internal directory, very widely deployed. And the transport standard, as you know, is SMTP, which is e-mail. The exchange standard, those who are using NHIN Exchange, NW-HIN Exchange, whatever, has a services registry, and that registry can be queried to discover entities and their exchange capabilities. UDDI and SOAP are two protocols. UDDI is Universal Description Discovery Integration, and that's a service oriented architecture standard for discovering services that have been exposed and they're available for broad use. SOAP is the transport standard used in service oriented architectures. The NHIN Exchange has a managed public key infrastructure certificate authority that provides their security credentials, and the transport standard is SOAP.

This chart shows the schema content and transport and query standards that were presented to us by these three groups, the IHE, X12, and XL7 OMG. The IHE Healthcare Provider Directory standard, as its schema it uses the LDAP schema, which is then translated into XML, that's the directory services, DSML is Directory Services Markup Language, which is just the LDAP schema translated into XML. For content they used the LDAP content plus ISO and the transport standards for query and response are DSML. DSML supports both SOAP and REST for the transport. REST is not really a standard. The standard that REST uses is HTTP, it's a regular Web, it's ... to use Web query in order to access services, is what REST is. Then the query language is LDAP. X12 uses X12 as its schema. This is their transaction 274, the provider directory transaction. They have a data dictionary that they use for the content vocabulary. They don't really define what transport to use. They do define the query as ITI 584, that's to query a provider directory.

Then the final one is the XL7 OMG effort. As I mentioned, this one is in its relatively early stages of development. The XL7 portion has been completed. XL7 has defined all of the requirements but OMG is really, so they've defined what is needed and OMG is defining how it's to be provided and the OMG effort is still underway. So the schema hasn't been defined, the content hasn't been defined, and they expect it to support both SOAP and REST and the query language hasn't been specified.

The functionality that's required, the IHE HPD supports all of the functions that are necessary for EHR query of an enterprise level directory for the services, for the entity itself, for its security credentials, and we have up there discovery of individual level provider information and locations as well, even though that isn't part of the current effort that's downstream. But we thought it would be useful to know whether it supports an individual level as well.

The X12 really doesn't support any of those. It's primarily a push transaction that allows provider entities to send a list of their providers that are members of a particular health plan. When they presented to us X12 very, very generously offered to work with this committee to adapt to the transaction 274 to support ELPD query functionality if we thought that would be useful, so we certainly appreciate that willingness to work with us from them. I've already covered the HL7 OMG. Well, I should mention that all of those are in scope as defined by XL7, but the standards haven't been developed yet.

This is our recommendations. You see on the left the four requirements areas. In the right hand column are the certification criteria that we recommend and then the standards and implementation specifications we recommend. Let me start on the right. The Certification criteria, which are really the functionality that's required is the capability to securely send to an enterprise level provider directory service a DSML query for entities and entities exchange services and to receive a response as specified in the IHE HPD profile. As you've seen, for the most part we're recommending, well, across the board we're recommending IHE HPD as the implementation specification but not the entire profile. As mentioned in the earlier slide, the schema that's envisioned for the ELPD is a very small subset of the whole HPD schema and LDAP schema, so it's really a subset of both the vocabulary and the schema.

The second certification criterion would be the capability to enable a user or software to list and select from the ELPD responses. We expect when you go out there and you search for Kaiser you'll get more than one response from that, and so they also need the capability to list, whether it be a human looking at the list and clicking on one entry in it, or whether it be software with some rules that drive it through and

say I want only those Kaiser organizations within 50 miles of me, so the EHR needs the capability to enable the list of the responses and a selection from among the list, and then finally the capability to retrieve the digital certificate for the selected entity.

The schema DSML, which is the same as LDAP, the vocabulary is LDAP plus ISO, the transport. On the transport, as you might expect, we had considerable discussion about whether it should be a REST transport or a SOAP transport, and we ultimately concluded that it should be whatever the Nationwide Health Information Network decides should be the transport for the NW-HIN. We know that right now the ONC is revisiting all of the standards around NW-HIN, in fact, we have a summer camp of activity in that arena, and we believe that the transport standard for the directory should be consistent with whatever the transport standard is adopted for the NW-HIN. And in either case it would be a secured transport, I want to make sure that that's very clear, both REST and SOAP can be secured, and in any case, as you see in the certification criterion, it would need to be secured. Then the query language that we're recommending is LDAP. The IHE HPD and the HPD, a federation profile is in development, so we're recommending that as well because we expect the ELPD to be federated. Questions?

Walter Suarez – Kaiser Permanente
Dixie, this is Walter. Just to add a couple of additional comments.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Sure, great.

Walter Suarez – Kaiser Permanente
To expand a little bit on the IHE HPD, as most of you probably are aware, the IHE profile goes through some rigorous development, piloting and testing. So when I mentioned that Social Security is implementing it in a pilot ... they did execute a series of proof of concepts through ..., the most recent one in 2011, earlier this year, where they demonstrated interoperability between Social Security, Epic, ..., Siemens and others. They also demonstrated during the HIMSS conference during the interoperability showcase the use of two use cases where they have been implementing HPD. The Social Security internally has a very strong provider directory infrastructure which is using the HPD profile. So there is a lot more than just simply an early test or a social context kind of a test.

Also on the HL7 OMG I just wanted to mention that while it is a standard in early development, in early release, I should say, because it's already a release one and it's more an abstract model, it has been approved officially as an ... standard. This was approved last year. So those are two elements that are important to mention. Of course the X12 standard, the ... approved standard has been introduced for a number of years already. So, just to give a little more perspective on the status of use of these standards.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that's really useful, Walter, and also another point that I intended to make here is that LDAP, Lightweight Directory Access Protocol, it's almost a de facto standard for directories within organizations, I would say it is the de facto standard for directories within organizations, so it's very, very widely deployed. But LDAP really isn't easily federated. In fact, the set of standards under LDAP don't really address federation. Federated, for those of you it means that you log in once and you really can access and navigate across multiple sites without having to log in every single time. So federation is really important here. LDAP has been federated and there are a number of ways that you can federate LDAP, but there's no real established standard in that area to federate LDAP. So DSML is an XML version that's really ideally suited for accessing LDAP over the Internet, so they're really the same thing only DSML is XML document oriented so it really allows the same functionality as LDAP over the Internet. So even though HPD has not been widely deployed LDAP most certainly has.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to John Halamka to kick off our discussion.

John Halamka – Harvard Medical School – Chief Information Officer

As I think about this whole problem, you heard testimony from the Massachusetts Health Information Exchange, we said what we needed to do was allow a query to occur over the public Internet that would result in a response with certain information about how to get information to a provider at a health information exchange. Now, we didn't have the benefit of reviewing all of these standards that exist, so what we said was, I'll tell you what, we will invent a query language, we will invent a vocabulary, we will invent a response format, and we will do this all over SOAP, and it's deployed today and it works very well. So in a sense what you've done is taken that exact construct and said, well, you've got to pick something for the query and language and oh, LDAP is used internally so let's simply use LDAP as a query language that everyone's familiar with. This does not imply you're using the LDAP standard in terms of its ports and the mechanism in which, it doesn't work very well on the Internet, you'd need SSL and VPNs and other things, so it's just the query language from LDAP but done in a Web-friendly fashion to be determined, whether it's REST or SOAP. We don't want "or" in anything that we specify, we want just one. We'd have to pick that. And when you say that we're using dismal, that's actually the pronunciation of DSML, it is not that this is a completely unusual and unused standard. It is purely an XML representation of the existent underlying, well understood LDAP schema.

So here we are faced with a challenge. We haven't really had health information exchanges that use standards for directory query in the past, we have to figure out a query, a response, and a transport form and you've attempted to say, well, generally what are the most used in the industry standards that will allow us to do that in a Web friendly way. Is that a fair summary of the work?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
That's right, and the other point is that because these individual level LDAP directories already exist within organizations remaining consistent with the LDAP schema and LDAP vocabulary it will make export and exposure of those individual level much easier as well.

John Halamka – Harvard Medical School – Chief Information Officer
With again no downside of the usual LDAP protocol itself requiring a lot of non-Web friendly transport.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Right, that's right.

Jonathan Perlin – Hospital Corporation of America – CMO & President
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Thanks. You always do tremendous work and it's really wonderful to see. As I look at the certification criteria the last one listed there is the capability to retrieve the digital certificate for a selected entity. Two questions related to that. First, is there more than one way to do that? I certainly can understand the notion of getting information back and forth out of a directory from LDAP and things, but are there more than one way to retrieve that information with a digital certificate? The reason I ask that is that in the direct specification they said we'll do certificate discovery using DNS, which is highly federated and I think pretty widely deployed, and I just wonder if what you're suggesting is that that capability be served by LDAP or whether other alternatives were considered and how the committee thought about that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Obviously, there are at least three, that I've presented today, ways of doing it: DNS, LDAP directory, and PKI, which is what NW-HIN .... So there are at least three ways of doing that, so yes there are multiple ways of doing that. What our certification criteria really addressed is what does an EHR, to be certified, need to be capable of doing, and that's what we say is that they, well, actually we probably should say from an ELPD. These standards really address how you retrieve it from the ELPD.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. I'd like to weigh in as well when you get a chance.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Great. David, please add right there if you want.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
To Doug's comment, I think the correct approach is to start with DNS, which only covers a subset of what the query capabilities need to be, but it covers the critical subset that Direct needs to get moving quickly and then to switch to LDAP at whatever time that becomes widely enough deployed so that it would work well, in other words so that the vast majority of addressed would be in a federated LDAP such that certificates could be fetched. So LDAP gives you a lot more than just certificates. DNS just gives you the certificates, but DNS can be used today and has been proven in the pilots, so that's what we wanted to start with, with the notion that we'd switch over whenever the time is right, which would probably be several years.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that's exactly right. DNS will give you two things: a numerical IP address, and a digital certificate if it's there. Our requirements from the Policy Committee were that the ELPD be able to give you how you get in touch with the entity, the services that they offer, and the digital certificates.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
You listed three functionalities, and what was proposed here is that there's a single standard around LDAP to try to produce that. But what I just heard from David was that currently the specification that we have in Direct says DNS, until such time as the LDAP is ready, the way that this is listed now it says that the capability is to use LDAP now as part of the certification going into Stage 2, which to me gets us in conflict with the Direct specification and it makes me concerned that Direct would then have to wait until the LDAP capabilities, if you will, were more broadly available down the road, two to three years from now. So when I think about this, I think what you've described is that there's three functions, there's certificate discovery, there's services discovery, and then there's also the ability to translate a human readable address to a machine readable address in –

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
No, that's not an ELPD function.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Let me clarify. Usually within an LDAP if I know someone's name, I may not know their full address or whatever, I'll enter that information and I'll either get an e-mail back which becomes a machine readable way of getting to them. You could get a postal address, but again that's maybe not a machine readable but it's something that machines read and they route the mail around and things. But it provides a mechanism of taking what I know about that person or organization and getting to how I would communicate with them, whether it's with a fax or a phone number, it gets me all that information. So those are three functions, right, this –

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Well, I would not include the DNS function as an ELPD function, no. I don't ELPD to replace DNS.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
But here what we've got is the capability to retrieve digital certificates for a selected entity. We're recommending LDAP as our approach and what David was saying is that Direct is not ready to do that just yet.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Some of them are using LDAP. David has covered this at a number of our meetings. David, why don't you explain where that stands right now?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

There was pilot code or reference code implemented to demonstrate that LDAP could be used to fetch a certificate, but I think Doug is correct, the assumption of the people who are implementing Direct now is that the recipient's address is already known, the textual form of their address is already known, and that DNS would be used to fetch the certificate to validate that that was in fact the legitimate address, that's not a directory function per se, but when directories are widely available the need for DNS, for certificate discovery would be diminished and could be eventually replaced by a broader set of directory services. But there was no intention to suggest that Direct should wait for widespread deployment of ELPD. We don't need that. We can start with what I call the business card model of transfer of address and use DNS for certificate discovery right away.

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David, the important thing is that DNS will continue to be used under LDAP as the way to do what DNS always does, that is, to find the IP address.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Oh, yes, the HIMSS record for the e-mail, SMTP part would not change at all. That's completely unaffected by any of this discussion.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think what Doug is asking is if we have as a certification criterion the capability to retrieve the digital certificate for selected entities from an ELPD is that going to close out some of the implementations of Direct that exist today? Or, as you suggested earlier today, David, that you would like to see the use of Direct as a Stage 2 Meaningful Use criterion. We don't want to say something that's going to be in conflict with another criterion either.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Technically speaking, the discovery of the certificate isn't part of the direct protocol. The assumption is that the HIST has the certificate and Direct could be validated with manual transfer of certificates. You could certify that a system can participate in the Direct protocol. The decision to how to distribute the certificates is incredibly important, because if you can't widely distribute them it will fail, that's why PKI S/MIME has failed in the past, not because protocol's bad, but because it's so hard to get the certificates distributed. So the DNS solution to certificate discovery is, we believe, a secure and workable and highly scalable approach that will carry us over to the point where widespread HPD would be available a couple of years in the future. But you could certify Direct without any reference to certificate discovery, and that's how I would recommend we do it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
So we could still have a criterion that required the EHR to be capable of retrieving a digital certificate using HPD and at the same time use the Direct protocol.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, I think that in terms of Stage 2 timing, given that there are a few details to be worked out around HPD, particularly around the federation point that you raised earlier, I'm not sure I would consider that a short term certification test, the ELPD part of it. Perhaps we would, but I don't think that's critical. I think the critical part is to make sure that you can actually handle the protocol correctly to do the S/MIME part and that the practical implementations would use DNS, although a site could choose to manage their certificates manually and just transfer them through other out-of-band means, that would be acceptable, certify the S/MIME, and I would say hold off on the HPD because I don't think we're going to be ready in time for Stage 2.

Jonathan Perlin – Hospital Corporation of America – CMO & President
See, this discussion's critically important. This discussion actually is ... to an action item today, which is to accept the recommendations. So I want to associate with Doug's framing, your presentation was just absolutely terrific, but we do have this thread that needs clarification so that it's not ultimately in conflict with either Direct or Stage 2, and then just note that. With that in mind, let's take the remainder of our time, which is limited on this discussion, to really work towards what exactly is the remaining clarification

and the notion of, I would offer provisional acceptance with that one area outstanding for completion. I know that online Nancy has her electronic card up, I saw Marc, and Cris second, so let's go to Marc and then to Nancy and Cris, and we'll stay fairly focused on this discussion because we'll obviously be coming back to it.

Marc Overhage – Regenstrief – Director
I may be very confused here, but I think I heard that LDAP's difficult to federate, DSML may allow us to federate, and the IHE specification might offer an answer but hasn't been implemented anywhere for real. I think Walter went through all the examples of where it's been demonstrated. I thought one of our core principles was that these things be live and in use somewhere, so I don't understand the provisional recommendation trajectory.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Would you have an alternative? We have a requirement to have standards for EHR query of an ELPD, so what would you recommend if we don't go with the one that is the most mature of any that exists today?

Marc Overhage – Regenstrief – Director
I think you have to have a trajectory that says let's develop that further so that it can be used.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
We have recommended, I know it's in tiny, tiny print, but the HPD federation profile, that's the one area that we think needs to be further developed. That's in bucket two.

Marc Overhage – Regenstrief – Director
Somebody's got to do it, Dixie.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Right.

Marc Overhage – Regenstrief – Director
Somewhere, somehow somebody has to have done it. We don't have that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It has to be done, yes.

Marc Overhage – Regenstrief – Director
I don't see how we can recommend it until we have that. In addition, at least I haven't seen anything that says that REST is included in the IHE HPD protocol, at least on their Web site it doesn't list it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
That REST is in which protocol?

Marc Overhage – Regenstrief – Director
IHE HPD.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It's not. When we met with them, DSML supports both –

Marc Overhage – Regenstrief – Director
You're playing fast and loose. You can't change it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
That's what our testimony told us, that it currently supports both REST and SOAP. That's what our testimony told us, so ask them.

Marc Overhage – Regenstrief – Director
I'd certainly like to see that documented.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay.
M
Our recommendations were under the assumption that the S&I framework process would harmonize some of the details to be consistent with other parts of the NW-HIN standard.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Right.

M
Particularly around REST and SOAP, because there is such a debate in that space. Rather than pre-define it, we said let's defer that to the integration process of S&I.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The federation issue is definitely one that belongs in bucket three that needs more development, no question, whether it's DSML or LDAP we need a profile for federating it, right? But the federation of the ELPD is really a requirement for the ELPD itself, not for EHR query of the ELPD. The EHR query just needs the one URL to go to, to query.

Jonathan Perlin – Hospital Corporation of America – CMO & President
... went away at this juncture because there are a number of threads that need to come together with some work in Stage 2, and Marc ... very fair point about what's been tested and adopted. On the other hand, we need to make sure that standards that are ready to support Direct are not inhibited by this process.

Jonathan Perlin – Hospital Corporation of America – CMO & President
What I was going to try to do was channel Farzad and David, because he always used to ask me these questions all the time. But if we were to not adopt this would it get in the way of getting to interoperability? The converse of that is, do we have to do this to get to where we want to go? The idea is these are probably the best ... standards out there to help us with directories. I think to Marc's point, SSA has implemented it in their infrastructure and it probably doesn't have widespread deployment across the industry. We know that for Direct there is a path going forward that would say let's use DNS as a mechanism for distribution now, but let's point in a direction that might be able to get us there. And we know also that HL7 and OMG is going to be working on developing a new specification that will be developed in the next year or so. They have a different kind of RFP process for how they do standards development with that. Even things like services discovery, DNS can help you with that certainly, and an MX record is a way of discovering your SMTP service, for example, or your HTTP service. You can even put, I believe, and you're the expert on this, Dixie, whether or not you can put in an LDAP entry in a DNS registry that it tells you where your LDAP IP address is that you're trying to locate those services.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Until Direct I didn't even know that you could use DNS to get your digital certificates. In fact, I don't think anybody has ever done that before the Direct Project.

Jonathan Perlin – Hospital Corporation of America – CMO & President
As a committee we have to decide if we make a decision is it something that is going to advance us, because we have to do that because if we don't do that we're going to end up in a state that's going to be wrong. Or if we make the decision now, do we lock ourselves in in a way that doesn't get us to the end goal that we want? Or, are we adopting something that is at this point premature that needs more work? And it could be that these are directional statements that we'd like to go towards, but that we need to do some more work with pilots, maybe we need to launch an initiative to think through some of those issues, articulate a path to get us from the direct approach, again, not well tested but has been used in some of the pilots as well. I'm just trying to frame this by saying, do we have to take action on this, because it's

going to get us in either a bad place or it's going to prevent us from getting us to where we want to go. I think all of this subject is tremendous. I think this is truly the state of the art that's out there now.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The state of the art, right.
Jonathan Perlin – Hospital Corporation of America – CMO & President
We need to think about if we put that into a certification criteria we're asking the industry to move in the next 18 months to get all these things lined up.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, I want to review how we got here. I completely agree that having an HER query have the capability to query something that doesn't exist is not logical, but we were told by the ONC that you needed this to include this in Stage 2. That's why we're where we are. I'm certainly not sitting here arguing that this needs to be out there in Stage 2. We're being responsive to our sponsor.

Jonathan Perlin – Hospital Corporation of America – CMO & President
What I believe I'm hearing is – I used to work provision I probably should have used conceptual, and I think Doug you're saying the same thing, is that there's a directionality intent here, but we shouldn't trip ourselves either by over-specifying things that we don't know will exist; on the other hand, we shouldn't not give ourselves and the broader community a signal of intended direction. I think there is a way to skin the cat, which is the further work which will have to occur off line from this activity, both in terms of input and demonstration. But you have the question still there, in the absence of this directionality, are we failing interoperability? I'd like to hear that question. Doug, I'm taking input, but you want to make a comment on this.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
This goes back to Carol Diamond's point early on is that if we believe it important from a security and privacy perspective that there's a certification criteria that a certain kind of function exists, the ability to retrieve digital certificates or the like, we can say that functionality needs to exist. We may not specify that it has to be LDAP or DNS or whatever, but that provides both a directionality as well as assuring that the functionality exists so that we can do the kinds of secure exchange that we'd like to see.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
For me what's more important is that they be able to validate the digital certificates. I don't care if they get it with the USB drive, but that they be able to validate that it's current and that it hasn't been canceled, ... entities. But that's not what we were asked to provide, so that's really – although we did include the validation ....

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. Doug, to your question, I think the Direct Project group would say, the people that are working on it would say that HPD or any kind of widespread directory service for discovery of addresses themselves is not necessary for us to proceed. That's one of the benefits of having used an e-mail moniker to denote the address. Those monikers are easily interchanged by people and the world lives on e-mail and there is no e-mail directory, so it's obviously quite feasible to manage a list of known addresses just simply by managing their e-mail addresses. You do need a certificate discovery mechanism, but the DNS model we believe will work fine. So strictly speaking from Direct's perspective I think the answer's no, we don't need this directory service as a part of Stage 2. On the other hand, we heard some very compelling use cases from the testimony from Massachusetts as to how helpful their directory service is. So I think there is benefit to directory service, but I don't think it's required for Direct.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's parse this into two pieces, the services necessary to support Direct, and further work on advanced services –

M
....

Jonathan Perlin – Hospital Corporation of America – CMO & President
I'm on Stage 2. To this point that David made, there are going to be 56 HIEs that are going to create separate provider directory systems – of course it depends on the architecture, if they use Direct or they use the ... implementation, but what you worry about is if we don't signal a direction that we're looking toward, and I think David said it very well, oh, DNS with certificates in DNS works for today, it supports Direct, but DNS isn't going to hold a whole lot of the metadata that we may want for exchange tomorrow, so looking toward an LDAP future seems very reasonable.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Plus, one of the examples that our group that did the assessment of Direct came across one of the use cases that I think really needs to be addressed in the near term is that if you have a Direct exchange you really need to know what service is at the other end to accept what you're sending. We talked about being able to send to a server that just received SMTP e-mail versus somebody who had implemented SDS and was prepared for an SDS transaction. So that's another thing that even Direct needs is the ability to figure out what the other end can accept.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's only take comments on this part at this juncture. Clearly, I think I'm hearing consensus around the ability to support Direct, and, Carol, thank you, as well as likely requirements for Stage 2 and parsed into those elements that we'll table today pending further work ... with the S&I activities and input that really clarifies it. I think that's a good way to parse it. Comments on that in particular, Cris?

Cris Ross – LabHub – CIO
I guess I'd try to humbly suggest there may be three issues that we need to untangle before we can come to a conclusion. I think what Dixie and her group have done is landed on a place that's entirely logical and reasonable. There may be some nit-picks, but the question is, is it a sustainable place given where we are. I think there are three things. Number one, we still have not done the work of matching up the Meaningful Use requirements against protocol standards, where we'll direct work, where we'll exchange work, where is something else needed. We just have divorced protocol transport from content and container. So if we're going to live in a world, for example, where we do need to do broad kind of query of either patient or provider or location, it's hard to imagine that without some queryable format of some kind, whether that's a directory or not.

Issue number two is the issue that John Halamka raised, which is these HIEs are building something, we ought to tell them something that won't get in the way of a future direction. LDAP is an industry standard, it sort of makes sense. The issue, though, with LDAP is that it is a standard that is not sufficiently precise to allow for consistent implementation everywhere. The federation effort described is an attempt to deal with that whole cloth. There may be some things shorter than that that are more best use, best practices implementation of LDAP, that might be very helpful, that wouldn't try to spoil the whole problem, but wouldn't get us into further problems.

I think the third frame that we need to look at is one of the advantages of healthcare being so unautomated is we get to learn from everybody else's mistakes, but I'm hard-pressed to think of an industry that has broadly discoverable entity level directories that are used in production for any meaningful commercial purpose. So it scares the crap out of me that we're going to try and bite off something that finance, retail, name your other industries that are highly automated, either avoided because it's untenable or they found ways to deal with it without directories. I think that's one of the reasons why Direct, for example, is a no directory standard, because they started with what's pragmatic and doable and now the open question is, without a directory and some other things, can Direct solve all the problems we need, and that gets back to question one. I think we need to solve those three problems, really, matching up transport with meaningful use case. Number two, do something that's practical that doesn't send us in the wrong direction with HIE. Third is figure out are we really trying to over-reach here as an industry.

Jonathan Perlin – Hospital Corporation of America – CMO & President

...in the form of a motion, if the rest of the group received it that way, but that they are work tasks coming out of this. I don't think that's exclusive of the immediate association of transport protocol for Direct, so I don't think it creates a barrier to activity. Jodi, did you want to weigh in before we –

Jodi Daniel – ONC – Director Office of Policy & Research
Actually, I was just going to comment that this has been a really interesting discussion, and it sounds like there is a sense of directionality here, but that from a process standpoint there are some open questions and some more information that folks on the committee are looking to have in order to think about standards for Stage 2.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Perfect. Then, if the group received that as a motion, should we adopt it as our workflow?

John Halamka – Harvard Medical School – Chief Information Officer
Can I raise one point, Jon?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Absolutely. Please note that the body language here was heads nodding yes.

John Halamka – Harvard Medical School – Chief Information Officer
Okay, good, because I can't see the heads. I like Cris' formulation, but I would point out that number three is really a policy question. This workgroup creates tasks by the Policy Committee to –

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes, I don't think the implication was that we have to solve all of those. We –

John Halamka – Harvard Medical School – Chief Information Officer
But back to that point, it was the Policy Committee that charged us with coming up with the enterprise level provider directory standards to support what they felt was a policy imperative.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Right, that's my point is that they gave us the task. We didn't try to over-reach on our own, we had help.

John Halamka – Harvard Medical School – Chief Information Officer
I will just tell you from my experience in Massachusetts that for a lot of exchanges unless every single participant in an exchange is going to build their own local directory, like we do for e-mail, everybody has a contact list, we're all going to have to have massive replication of every provider's address everywhere, and it would certainly be nice to have a community queryable directory and not specifying the schemo or the details of how you do it, but just how you do the query and response. So I'll, in the meantime, continue to invent in Massachusetts, but some day I might want to query, say, Connecticut.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And they are recommending, I would remind you from the earlier slide, this enterprise level has a very limited set of information, basically to get from here to there.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. Jim?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I want to make a suggestion about either the motion or the way we proceed. If we're going to send a signal, which I entirely agree with, we want to make sure it's as much signal and as little noise as possible. I think it ought to take something like the form, this is what we're sure of, these are the open questions that we're addressing, and we will come back to you on date certain, pick a date, and tell you whether we've solved the outstanding ones or whether we're still working on them.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I agree with that conceptually. Let me ask Doug Fridsma to weigh in, just in terms of making sure that our notions of calendar and directionality are consistent, agreeing entirely with the principles behind that.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
I think that it's been tremendous. I think one of the things that we should think about, and I like how the question's been phrased. It sounds to me like there's some work that needs to be done. In the HITECH legislation, I was just getting a sidebar here with Jodi, there's very specific things that happen that if there is a formal transmittal letter that has specific recommendations in it, it sets up a 45 day review process and a letter that goes to the secretary. So the question is, if we recommend standards implementation specifications and certification criteria and we put that in a transmittal letter as recommendations, the secretary has to decide. So we may want to think about how we want to, with regard to the motion and the committee here, frame this. Is it something that we think the secretary should put something in the federal register, or is this recommendation perhaps to ONC or recommendations for future work, or other things like that that we need to consider. We just want to make sure that we fit it into the process and the whole notion of recommendation carries with it a lot of legislative weight that we have to consider.

Jonathan Perlin – Hospital Corporation of America – CMO & President
One clarifying question for you, Doug, is would not the pieces of our discussion today possibly align with different components of that broader vetting? For example, are there not some simpler elements that are related to support for Direct that would naturally converge with the workflow that we've established, recommendations to ONC, and there is more complex consideration of future directory services and discoverability that frankly we have to do some homework that we've done ... entered into the recommendation process in terms of the precision that Jim challenges us to. Jodi –

Jodi Daniel – ONC – Director Office of Policy & Research
Let's see if I can just jump in. If what you're suggesting is recommendations to ONC about what we do with respect to the pilot that we're doing, I don't think, I'd have to look, but I don't think that would trigger all of these requirements. If it's a standard that we would be adopting as part of our rule-making or that we'd be considering as part of our rule-making then it does carry all of that weight with it. I think we can work with you on how to represent some recommendations.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, to recap the bidding, we have one body of work that is necessary to support Direct and the articulation of Stage 2 for Meaningful Use. There's another set of activities that relates to the broader discoverability and exchange process. It has both discrete elements of what standards need to be employed, as well as, frankly, a philosophical question of whether discoverability is necessary and appropriate in the broad. I would ask on the first part that we want to make sure that if we're ready that we support, and perhaps Dixie could enumerate the ... standard so that we're very clear on that aspect, and then frame, why don't you take the question and then we'll work with you and ONC on the latter to frame that for subsequent activity. Carol, do you want to –

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I am. I don't think we can make a decision about standards until the three elements that Cris Ross outlined, the three questions are further developed. I want to say from a process standpoint I'm struck by Dixie's understanding that the challenge that was put to you was maybe not one you would have chosen for yourself, and I would just ask that there should also be a dialogue to refine the requirements that are necessary right now. Anyone who has ever taken business requirements on the technical side knows that the first version you get is never what you really end up with, is never what you build. There's a process of back and forth and really understanding what is the objective, the interoperability objective, that they're trying to fulfill here. I think if we can get that more clearly defined, it may take us to a slightly different place, given the reservations and the caveats that we have about whether this is feasible, practical, what have you, as a sidebar. In other words, I think there's some refinement of the request also that should happen with some technical advice in that refinement.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay. Can the Privacy and Security group work with ... and ... to bring back a parsing of that. I think it's fair that we're not ready to act as a group on that. But let's be sure that we don't get in the way of Direct or those immediate requirements for the timeline that Paul and George laid out for Stage 2 and realize that you've obviously come to the table very prepared but perhaps further downstream, the evaluation that is requested here.

Doug, I want to make sure that in terms of the timing and requirements that you're seeking that this will work.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Yes, I think that this will work. As I said, this is a thoughtful analysis of what the current state of the art is. There's just no question that that's the case. I think, to Cris' point, the state of the art out there and what's been deployed and implemented is challenged and I think to John's point the one risk that we see is that there's the concern that things might get diverged, if you will. Lots of people are doing things in lots of different ways. But I think that there is a very strong sense of directionality here, that we do want to use standards that help us discover certificates and get the information that we need around providers. I think if we can support some of the transports like Direct and Nationwide Health Information Network and the other specifications there, I think we can get what we need with this.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I'm estimated that we're prepared at the next meeting, at least on that first step, the Direct transport bit, and fundamental transport standards.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay. We'll work off line. So the motion formally is on the table ...., a lot of work between now and our next meeting and I appreciate everyone also committing to that work in that time period, Jim.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I did see there's also work on the Nationwide Health Information Network that you'll be leading, and I have a feeling, Doug, that to your point, this question will be part of that analysis too.

W
Yes.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
So to me if we say temporarily we're recognizing that for Stage 2 we're accepting Direct and the DNS queries that have been outlined, but there's a series of questions that will lead to pilots and we will also dovetail the analysis with the NW-HIN review.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think that's the perfect framing. I also think it's an obligation that we not give mixed signals about the support of Direct and the capacity that exists now. Terrific, if there are no disagreements we'll .... We have our work cut out for us. Please know, Dixie, that we also appreciate you, Walter, and the rest of the committee and the huge amount of work and the thoughtful consideration of all the input and the testimony, etc. that went into that. We do have an obligation to act in terms of providing a signal, so that the future is not ... but at least oriented around some general thinking until such time as standards can be ....

We're running late. These have been very rich and thoughtful discussions. I note the update on the Clinical Quality Workgroup is very brief, and so let's put the pressure on Jim between now and lunch to be very succinct. I believe the slides are actually fairly succinct, the four slides that are there.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
The committee is working well. We have no recommendations to make for you to consider. What we have continued to do is stress the quality data model and so far our conclusion is that it can manage every data management need that we've identified. Tomorrow we have a hearing with a very wide spectrum of implementers, manufacturers, others to tell us about their early experience with the complexities of implementing MU1 quality measures and any thoughts that they have that might help us in making MU2, particularly quality measures, more useful and more implementable.

That I think will be a productive day. Then beyond that we are actually, since these slides were created we're creating power teams that will work with Floyd Eisenberg to work through specific measures and look at vocabulary needs and other standards needs related to those. So we anticipate having some concrete findings for the next meeting.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I appreciate the brevity and look forward to the hearings. Any comment or input? Marc?

Marc Overhage – Regenstrief – Director
Just a quick question, Jim. I don't mind staying between lunch. I don't need it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Actually, just for the record I realized I short changed the implementation. We're going to have a relatively ... report there as well.

Marc Overhage – Regenstrief – Director
Just a short question, Jim, which is, is there anything that would help the committee move forward? It seems that there are some struggles with clarity of questions to be answered, and are there things that the group could benefit from if we can collectively make happen?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I think right now the issue has just been working out a shared understanding of what the scope of work is. I don't believe there have been any specific questions that have limited that. I do think the earlier discussions about core and menu is probably going to simplify and clarify our work tomorrow afternoon. So that's been useful. I don't believe that those are the issues right at this point, I think just general clarity about what the scope of work is and what the specific questions are.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Judy, please?

Judy Murphy – Aurora Health Care – Vice President of Applications
I feel like we've really spent a lot of time looking at the meaningful use measures for Stage 2 and we've been getting reports at each meeting, but I don't feel like this group has vetted or talked much about the quality measures as it relates to the standards. When I think back to Stage 1, these were sticky wickets for people and the standards in particular that were articulated in these multi hundred page documents related to quality measures. So I do feel like the sooner we can weigh in the better, because the clock is really ticking.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I totally agree with you. That's one of the issues is the discussion, the thing we've had today, exactly how much – I love Carol's analogy, that's the perfect analogy. You get a spec and you know that you're going to have to have three or four iterations before you understand and before actually the person requesting the service really understands what it is they want, and balkanization isn't a bad term, it's just hard to have those iterations fast enough and some of them usually need to be face-to-face. It's often very complex work that you're doing trying to get a shared understanding of what the scope is, what the questions will be, what the deliverable should look like, so I think it's just relatively predictable startups since getting ready to work.

W
So the question is the timeline, and maybe this is for Josh or Elizabeth, is the timeline on the quality measures the same as the meaningful use measures, meaning they're supposed to get turned over in June, right?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
It's been hard to get agreement on the timeline also.

W
We're going to propose the quality measures in the NPRM, so we're going to need them by August. So our Office of Clinical Quality and Standards is working to make that happen. And just like we did in the NPRM when we proposed 90 and we had to ratchet it back, it will be something like that, where we'll be hoping to get the final electronic specifications for as many as we possibly can, but it may have to be ratcheted back, depending on what we actually get in time.

Jonathan Perlin – Hospital Corporation of America – CMO & President
John?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer We certainly accepted as a given that we have to work as fast as possible.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Just for clarification, I think that's one of the important triangulations is that CMS ... also part of Jim's charge in the reconstituted Clinical Quality Workgroup was to make sure that the measures were as efficient and practicable as possible in terms of implementation. So there is a triangulation there that's limited by forces outside. Josh Seidman, ...

Josh Seidman – ONC
I was just going to say I think the goal is similar to Stage 1 where in the NPRM we laid out the measures or the potential measures and by the final rule to have the full electronic specs available. So that's the timeline.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I just would state the obvious, that this group, as all of our colleagues learned that good measures are difficult in their own right, both in terms of the basis, the evidentiary basis recommendation, as well as the validity of our liability measure itself, allowing them to have those same qualities when represented electronically where the data that might be utilized in a paper-based environment or with human auditors is very different than the electronic representation. And so bringing those sorts of lessons together is I think going to be one of the important pieces of the work of the Quality Workgroup going forward.

Josh Seidman – ONC
Agreed.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think that the time pressure on that is apparent. The other is that I suspect we're still getting feedback on the current practice. Kevin Hutchinson?

Kevin Hutchinson – Prematics, Inc. – CEO
Just one quick comment. I'm going to come back to the statement I made earlier that we didn't address, but it is really tied to this group, because if we're going to focus on the Clinical Quality Workgroup and Meaningful Use 2, and I know I've put a business head on it and said what is the goal that we're trying to measure with respect to decreasing hypertension, increase in how we manage diabetes, compliance, because it seems as we're getting closer and closer to these Meaningful Use 2 standards in the Clinical Quality Workgroup, if we're just going to throw out reporting around certain conditions but we don't know at the end of the day if the technology, the interoperability, the EHRs and these other things that we're really striving to deploy are having any impact, I mean, there's plenty of examples where there's been impact, right, controlled examples whether it's Kaiser or others who have reported on certain aspects of

conditions that have been improved upon through the sharing of information, and it just seems like if we could rally around both the Policy Committee and the Standards Committee around two or three major clinical items that we are going to achieve by 2015, then it gives us some basis by which to establish standards work that needs to be done to achieve those goals. Now, I know that's probably outside of the purview of this organization, I recognize that, but I just think that if we can push that up, that would be helpful.

M
Yes, I would agree with you, Kevin. I think the problem is it isn't anybody's. The people that care about it, it isn't their purview. And the people whose purview it might be it may be too low level for them.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I appreciate that. So I think it does challenge us. I appreciate ... representing CMS. There is an agency .... I think the council is good and I think the way we influence that process is that indeed the measures are reliable, valid, evidence-based when they're brought to the electronic world. So I think it can go back into that broader process. I appreciate those points.

We've got a lot of work left this afternoon. Doug, you will probably be more succinct through ... of activities, through the different summer camp activities. Let's have a quick overview of the implementation because I want to make sure that we respect the public comment period, because this is a Federal Advisory Committee and that is just one of the sacrosanct pieces. So I want to turn to Judy Murphy and Liz Johnson, and then after that I promise we will take a break.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
And so the pressure increases, great. So we'll go ahead and go to the slides then.

Judy Murphy – Aurora Health Care – Vice President of Applications
We can cut it down from 30 to 20.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
.... as we notice the glares around the room we're just saying that's probably not the correct answer. Let's go to the next slide, please. As always, we want to thank all those who are contributing. We've had multiple meetings to compose a survey that's now posted out on the federal Web site, and so thank you to all those that are listed here for your contributions. Next slide, please.

For those of you who have joined us on the phone please use this Web site because when we go over the survey it's not on our PowerPoints, it's too difficult to try and do that, so you'll see posted here that there's our usual FACA blog out there that will take you to the actual survey, and you will need to do that because it is posted, it was posted actually Monday. Next slide, please.

In essence what we did was we took a challenge that was put forward to us by this committee to say we've gone through certification once now, it is temporary in nature, moving to our permanent, but we know that there have got to have been some opportunities that we can take advantage of and adding advice to the future certification process. And we made the decision that we would first formulate a survey and collect comments from a myriad of stakeholders, do the analysis on those comments and bring them back, and then consider a public hearing. So as you see here, that survey is now posted and again this is the actual page that you'll go to before Judy goes over the survey.

Let's also talk about before we go over the survey the timeline, which is our final slide, but we have a survey to go over. Next slide, please.

We released the survey on Monday. It will close on the 17th of June, which gives people adequate time to give us information and add their comments. We'll then compile and summarize the survey in the month that follows that, we'll analyze results and formulations and also determine at that point do we have adequate information to come back to this group with a list of specific recommendations for changes in the certification process and scripts. Or, do we want to also have a survey. We have not made that

decision yet. We'll present those recommendations to this group and that will be at the committee meeting on the 17th of August. There will be immediate clarification, no recommendations, so there's something that's still going on around Stage 1, because remember everyone's not finished with Stage 1 yet, as well as future recommendations for Stage 2, and then we'll disseminate those recommendations in the September/October time frame. With that, I'll give it to Judy to talk a little bit about the survey.

Judy Murphy – Aurora Health Care – Vice President of Applications
Very briefly, the next handout in your packet is actually a copy of the survey. And just to point out for you and/or any constituencies that you're working with, you can either post your comments right on the blog, question by question, generically, if you will, or you can download the document, complete the document, and e-mail it in. There are 17 questions and so it might actually be easier to download the document and e-mail it in. Either way, all the information will be compiled in the same manner, whether it's off of the blog or off of e-mail. I think with that we'll close. I won't go through the questions. They're obvious it's on the survey itself along with the background information.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I appreciate the brevity and the hard work that is behind ... engagement. Could you comment a little bit about the analytics, because a number of the questions are open ended in terms of what people responded to positively or want to see changed in the certification process.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
It is not going to be an easy summary to summarize. So it will be like what Josh had to do with the meaningful use comments when he had 487 and they were all texts. But we did feel like we really did need to do that. And we are going to break it up by constituency and summarize it first by constituency, and that's listed in the first question. Is it an ATCB responding? Is it a provider who is attesting? Is it a provider that had to self-certify, and then we'll take that all and compile it together. Now, there are some yeses and nos. So we will at least have the percentages of yes and nos. But of course if they say no then we're asking give us an example. We've also asked things like what are your top three issues, and we do expect to be able to pull that together into categories, but we didn't want to recommend the categories because we felt then that was going to be a little bit more directive. We actually had a very lively couple of conference calls putting the survey together, so I'm thinking we ended up with something that's going to be informative, but that's why we're holding out on possibly still having to have a hearing.

One of the suggestions for the hearing, just to give a little bit more background, is there are a lot of organizations doing their own surveys, not specifically about certification but about the Stage 1 process with some sub-components related to certification. So one of the thoughts was at the hearing we'd have HIMSS, for example, or CHIME, or AMIA come and testify as to the survey they did and what they found out, because it might be quite informative to us, although there's also a specific reach by some of us on the committee to make sure those folks weigh in formally through our survey as well. Does that make sense?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
....

Jonathan Perlin – Hospital Corporation of America – CMO & President
Indeed.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Did I talk fast enough?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Completely. Any comments, questions from the committee?

Judy Murphy – Aurora Health Care – Vice President of Applications
This is Jon's new approach to getting us back on track, is that correct? Very nice.

M
It worked for ... seminar training, it works for us.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, terrific work of the committee. I really appreciate the engagement this morning around some really very thorny and complex topics. Let's break until 1:30 precisely and then we'll go through vocabulary and then ... summer camp. Thanks.

... our after lunch meeting with the report of the Clinical Operations Vocabulary Taskforce. Remember, as we said at the last meeting, that we want ideally one vocabulary per domain and to the extent that there are other vocabularies necessary, cross-maps, and we'll hear from Jamie as to what is the current parsimony of vocabularies per domain.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. We have managed to have several meetings of the Vocabulary Taskforce and we have actually recently established a more extensive schedule going forward, because we have more work to do. Our current priority is to work on developing recommendations for the vocabulary standards that were requested by Doug Fridsma in our meeting two meetings ago, I think, being medication vocabulary, both for ePrescribing and for medication allergies, lab vocabulary, both for test results and for test orders, and problem vocabulary for problem list documentation. I think it's actually important to say what it's for in the statement of that request, so it's not just lab vocabulary, it's lab for results reporting versus ordering, for example, and I think those are important distinctions.

Our process then is first to assess the previous vocabulary recommendations of this committee because we have had a number of transmittal letters that included vocabulary recommendations. We had started by reviewing those. We want to assess whether the recommendation is still valid. We want to assess the readiness of the vocabulary itself, the supporting technology, and industry readiness, so the feasibility of industry-wide implementation for Stage 2 and/or Stage 3.

We wanted to pose up front a general question that we've come back to as a result of these deliberations, and that is whether or not it's possible to have a certification requirement precede a meaningful use requirement to facilitate adoption. For example, the implementation of the standardized vocabulary for medications, which is most of my presentation here, is something that if the EMR is capable of it and if the vendor has supplied that sort of support, then the prescribers, in that case, can go through a multi-year process of implementation, testing, clinical validation and so forth, but that can only start after the support for the standardized vocabulary exists in the EMR. So that's an example of where this question would come into play, whether it's possible for us to recommend and whether it's possible for the rules to implement a requirement in certification before CMS would actually measure the use of the standardized vocabulary.

John Halamka – Harvard Medical School – Chief Information Officer
... walked in. Jamie has posed a question, which is can you decouple certification and meaningful use. And he makes a very compelling point, and I think of them as separate regulations, that is to say it's hard to get meaningful use of vocabulary unless it's already baked into the software. So you can imagine saying the next round of regulations will require a ubiquitous use of SNOMED so the physicians get familiar with it, learn how to use it, novel interfaces are created, but it doesn't become a meaningful use requirement until later. Poor example, but that's the gist.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Most of our discussion here today will be about medications, but we've specifically, as a workgroup have discussed that for the implementation of RxNORM for medication orders in that the vocabulary would need to be supported in the EMRs and then a transition to its use in clinical use could begin. Speaking of RxNORM, which was our previous recommendation for medication vocabulary, I'm really going to divide this up into two questions. I'm going to try to go through this fairly quickly to keep us on time or get us back on time.

The first question, which is covered on page three here, is whether the vocabulary itself is ready for adoption. The second question is whether the industry is ready for adoption. So in terms of the vocabulary itself, there are a few things that are still under development, in fact, some requests to the National Library of Medicine as a result of our workgroup meetings, are to add to RxNORM the most frequently prescribed over-the-counter drugs so that a prescribing subset of RxNORM then would include all the items that are most frequently prescribed, not just necessarily prescription drugs. So the NLM does have poised for publication an ePrescribing subset of RxNORM that's just prescription drugs, and so we will help them through a process to find stakeholder input on the non-prescription drugs or the OTCs that would be added.

Now, we do have an initial recommendation with regard to RxNORM for the use of the vocabulary, which is that four components of it should be required in ePrescribing, that's the ... clinical drug and the ... branded drug, so basically the branded and generic, and the same for packaging, branded and generic packaging.

Then moving on to the question of industry readiness for RxNORM as the medication orders vocabulary, we've heard that basically the pharmacy industry, represented by NCPDP members, is expecting it and working towards it, that all the drug information providers have either completed or almost completed their mapping of RxNORM, that Surescripts is getting ready for it, and at the same time we need to get more information from some stakeholders in terms of their readiness. In particular, we have not reached out to nor heard from EMR vendors, a variety of provider organizations, or other stakeholders. The pharmacy and drug information industry is ready for it, but other stakeholders were not ready and able to assess their readiness at the same time, so that may indicate that we would want to perhaps delay a recommendation on this.

But there is use of proxy NDCs currently in medication orders that we've heard from a variety of stakeholders is very undesirable. So there are counter-balancing forces for moving forward very quickly, versus needing to enhance industry readiness as well as some of the OTCs in RxNORM. We do think that there's a need for piloting and evaluation of the ePrescribing subset that is, as I said poised for publication by the National Library of Medicine, and we haven't yet worked on how or when that might happen. But I'm not sure that that would impede the adoption of RxNORM for Stage 2, certainly for certification. Let me pause here and ask if there are questions on the vocabulary for medication orders. Okay.

Then for medication allergies we've also had some discussions about the use of both RxNORM for the active ingredient components, as well as the UNique Ingredient Identifier, UNII for the inactive ingredients and also potentially for non-drug allergies certainly which was part of the committee's previous recommendation.

I'm going to move on now to labs, and so the intention of the taskforce is to tackle medications first, then labs, and then problems. So we're taking our work in that order, so the lab recommendations are up next. We have had some general discussions about it. We noted that LOINC was previously recommended for results, as John said earlier, including SNOMED organisms, the Bethesda terminology, which is also part of SNOMED for PAPs and so forth for lab results. Lab order vocabulary, however, is a really different beast and so in the first place there's not acknowledged or widely used standardization of order messaging. So in order to identify vocabulary for lab orders we need to do that in conjunction with standardization of the messaging, and then the objective really comes into question because there has been promotion of a standardized representation of a drug order compendium that's really just taking the current codes, whatever they are, and putting them into standardized messaging representation. That's very different from actually standardizing order codes, which would go along with the industry move towards unique test orders.

So today most commercial labs do not support UNique test orders, they support their own panels and profiles of tests that they publish in their own compendia and so one possible path in the road would be to standardize the representation of those non-standard compendia, if you will. And another possible path

would be to actually standardize the test order codes, which would then require really as a prerequisite an industry-wide move towards UNique Order Identification. The UNique Order Identification may be easier in some cases for hospital labs to support, but is not widely implemented throughout the U.S. today. Again, let me pause here and see if there are questions and discussions on the lab order and lab result work.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I would remind us that this LOINC SNOMED question has really a decade or more worth of inertia behind it, and the mantra had always been if SNOMED is the answer then LOINC must be the question. Specifically meaning that LOINC would be used for tests as such and SNOMED would be used more for results. In a micro context that's actually quite obvious, where the microbiology test itself would be a LOINC specification, whereas, the answer or the result could be presented in a SNOMED context. I think it's important to maintain that perspective and not conflate the notion of a result with an order.

John Halamka – Harvard Medical School – Chief Information Officer
Doug, just a clarification. I do not believe that standardization of lab orders is something that is currently a proposed Meaningful Use Stage 2 criteria. Obviously, LOINC, when available and results in electronic results that orders –

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
We don't understand that as a Stage 2 proposal either, but if it's going to be proposed for Stage 3 then this work would have to be done in advance.

John Halamka – Harvard Medical School – Chief Information Officer
Certainly as we've talked about, one of the goals of the S&I framework is to come up with simplified, lab implementation guides that significantly reduce costs, and I would argue much of my cost is on the building of the compendiums for ordering. So certainly directionally it seems the right thing to do.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
If there's nothing else, then moving on to problem list. Again, our plan is to attack the problem list and the problem list subset recommendations after the lab, which is up next. Just to review that the previous recommendations of the committee were for problem lists to use either SNOMED or ICD-9 for Stage 1, either SNOMED or ICD-10 for Stage 2, with the timing of ICD-10 for the HIPAA rule, and moving towards SNOMED alone for certification in Stage 3. So that was our previous recommendation. Then we had a discussion this morning with the Meaningful Use Workgroup and the committee here today, talking about whether a problem list is a catch-all or whether a problem list is just for problems, meaning disorders and findings. I think we heard clearly from Paul Tang that the intention from the Meaningful Use Workgroup perspective is that the problem list should be used for disorders in findings and not as a catch-all to put procedures and regimes for therapies and medications and other things in.

We also then did have some discussion about tempering that with it being whatever is present that may require intervention as the measure of what would be in the problem list, but what that can do for us from a vocabulary subset perspective is for certification purposes we could limit ourselves to a subset that is just disorders in findings and perhaps situations. Then because there are published subsets that are nicely small enough to be easily testable, in the 1,000 to 2,500 term range, that are the most frequently used problems in those categories, whereas, the other subsets are the broader ones that include a large number of procedures and therapies and so forth. Now, let me pause here for discussion on this.

Jonathan Perlin – Hospital Corporation of America – CMO & President
As people that know me anyhow realize, I'm fascinated by diagnoses and findings. However, for problem lists it's not infrequent, as Jim had pointed out this morning that situations and circumstances that can include therapies and procedures are highly relevant to the problem list, for example, status post heart transplant or presently on immunosuppressant therapy. Those are not diagnoses as such, but they clearly dip their toes into the procedural and therapeutic space in a way that is relevant to the problem list. So we have to be very cautious about waving the diagnosis and finding flag exclusively for problem list characterization.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. I have a question.

Josh Seidman – ONC
Please, David, go ahead.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I'm always a little bit confused by the notion of these subsets and what it means for codes, legitimate codes that belong in the problem list that aren't in the subset. I understand why we conceptually like the idea of a subset, but what does it actually mean? Would a subset be the only codes that you're required to support and any more granular codes are optional? Or, is the subset what's in the pick list and more granular codes require a different kind of look up? What would the certification implications be of a subset, I guess is my question.

Josh Seidman – ONC
I'm going to start with a thought, is that recognize if we had a Web site where a set of vocabularies and code sets were downloadable as a minimum floor, a starter set that were the most common, I think Doug used the term "80/20," it's your 80/20 problem list, your 80/20 lab compendium. But then, should a new and novel concept come your way, you should be able to incorporate that. But it's a starting point.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Right. So we would call these a convenience subset.

John Halamka – Harvard Medical School – Chief Information Officer
But it's unlikely that you could get away without supporting a broader—I mean, specialists are going to dive deep into classification of their particular specialty. They'll undoubtedly go outside of the 2,000 item subset. I mean, even the 6,000 item core subset doesn't contain some fairly common diseases.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
This is Wes. … did you want to respond to that further?

M
No.

M
Anyway, go ahead Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I just wanted to re-ask the question that David asked. What are the certification implications of a subset? Is it that the only thing that is required in certification is the subset, but that implementations are free to add over the subset as they wish? And if so, are we clear that the subset includes all of the problems necessary to generate all of the data for the quality measures?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. I think, Wes, that you have it right on both counts that the intent of the subset is to be the minimum required for certification, that implementations certainly would be free to use more than that, and that subsets—we've talked about this; I didn't mention it, but we have talked about it on our task force calls—is that subsets would have to include anything in the enumerated list of codes that's in the value sets used in any of the quality or performance measures. And so that's a cross-check when the electronic form of those measures becomes available, so there is a dependency there.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thank you. I think we also need, then, to certify the handling of an incoming code that an EHR doesn't have in its table of codes. I think there's a reactional way to do this, which is through some sort of

process that includes that data with a code that says, “not identified” and text that provides additional information. But I’m concerned if we don’t do that, then we generate a huge interoperability mess.

Josh Seidman – ONC
We know Postel’s Law that we keep talking about is that we should have a set of codes that are our starter set, but should a new code be encountered, it will not break the system.

M
You know, what comes to mind for me is that this may be an area for functional certification criteria to be developed because it’s not really an issue of the standard as to how the certified EHR functionality handles lookup of a code that’s not in the minimum subset.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. I think the David … scripts already pretty much testify that you verify interoperability with a functional test. That is, you see what’s displayed in the system, and I think it just needs to be extended, if it hasn’t already been extended, to this particular case that we’re describing of an unknown code coming in.

Josh Seidman – ONC
The whole intent of this body of work is that we’ve all talked about that from an implementation workgroup perspective, if we had an easy to download starter set of vocabularies and code sets, it would accelerate interoperability, novel product creation, etc. So, at least, I don’t perceive your discussion as coming up with the end all for certification as much as it is empowering people to use controlled vocabularies; when we say you must use SNOMED, here’s a starter set.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Well, I think that’s fine as far as it goes. But you can’t write a certification script that says … law. You have to write a certification script that says what that means, and that’s really all I’m asking.

Josh Seidman – ONC
Jim Walker

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Just my ignorance, sorry. So if a system receives a SNOMED code, it is part of certification that it can consume it as a SNOMED code and manipulate it as such?

Josh Seidman – ONC
Not clear. Right? That is to say if what we are talking about, and let’s take one of your domains, that you said that problem lists will be codified in SNOMED. Let’s take that one. So our internal system may use whatever, but when we transmit the problem to some other party that we would represent the problem with a SNOMED code. I think that’s the notion of interoperability here. You could use proprietary code sets internally, but as it goes external over the wire, for interoperability, it’s SNOMED-based. So hence, if there is a recipient on the other end, they will be receiving a SNOMED code and will have to do something with it such as display a human-readable translation of it, or map it to one of their internal representations.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
So the scope of certification doesn’t include doing things like saying that a certified EHR shall be able to manipulate SNOMED codes as such. It seems to me that’s something that is an important protection for implementers for healthcare organizations, but we’re saying that’s out of scope for us?

Josh Seidman – ONC
My sense is that when we as a committee have come up with standard certification criteria they apply to data which is exported from an internal system to another party. So it’s SNOMED over the wire.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

This is Wes again. I feel like we may have more differences than appears here. Currently, when an EHR is certified as a user of an e-prescribing product, the certification includes that it can actually do something with the data that it receives. It doesn't care what the internal format is. For example, if we were to say that this is the floor for the number of SNOMED codes per problem, and those codes drive either data aggregation for reporting for quality, or clinical decision support, or whoever. There ought to be some operational/behavioral steps that NIST can write a script for that says, yes, it achieved it and dealt with it semantically, regardless of what the internal format used for the code was.

Josh Seidman – ONC
And, Jamie, just reflecting with you again, I think your body of work is more about accelerating EHRs to have a starter set, than this is about creating some certification.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well I think that, Wes, what you're talking about, frankly, makes a lot sense to me but it's not in the scope of work for making the recommendations out of the vocabulary task force. But it's certainly something that if the committee agrees, we could assign that task of creating those functional criteria.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I think that we should know whether NIST is going to be charged with doing that or not because it may reflect on the deliberations of the committee.

M
… very much so. As many of you know, I think it's terribly important to distinguish between starter value sets and overarching domains, and then behavior of those domains. The notion of having a U.S. realm, which would have, as a federal service, the designated vocabularies available through Web-based APIs (common terminology services) is a very old idea. It's at least 15 years old.

And if we're going to maintain a functional management of a term that is not part of the starter set that would be feasible, scalable, achievable, (certainly for phase 3) then the requirement of having as part of certification—of having systems be able to invoke a federal network of terminology services so that they can look the darn thing up and display it to a human being—I think is going to crucial.

It's inconceivable to me that we can talk about semantic interoperability without having some meaningful way (if we're going to talk about meaningful use) of managing codes that are not in a starter set or are not locally stored. We need to have some way of managing that.

So I would posit that one solution for that is for the once-and-future U.S. realm to support a body of terminology services that would be widely published, openly specified, and available. And I would add that this week in Florida, the final version of Common Terminology Services version two was presented at the HL7 meeting in partnership with OMG. So I think there is a specification that is obvious and available so that we can have, whether it's hosted at NLM or wherever it may be hosted, a body of content that would be query-able by services for those codes that are not managed as part of their local subset.

John Halamka – Harvard Medical School – Chief Information Officer
So I think the question that's been left on the table is, Doug, from ONC's perspective, rather than just propose that these are the vocabularies that we will specify from a standards perspective and provide starter sets, are there certification criteria that you think should be assigned to this task force as to what functionality NIST might want to test.

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
So, thank you. And Chris, as you know, we're working hard on a U.S. realm, so give it some time—another 15 years; we'll get it. So I think there's two things, I think one of the things is that we want to provide to the industry a very strong directional statement or a directional focus. I think one of the things that we hear is that when we say SNOMED, CT, or ICD-9, or ICD-10, those 'ors' are translated into 'ands' whenever the vendors have to manage that.

If we don't scale the problem, it becomes really hard to say, "Well listen, we were really using ICD-9, and now we'd like to use SNOMED, but how do we map all the codes, and how do we manage our internal systems, or are we using something proprietary?" We'd really like people to be able to move towards that world in which we have that semantic interoperability, but to figure out a way to do that incrementally that allows people to have success as they move through those various stages.

And so, I think I agree with you that having the ability to query a series of vocabulary services is something that we want to be able to enable. But I think getting there too, we also have the ability to say—there was just an outbreak of H1N1. The CDC has identified a new test that needs to be done. We don't have it in all of our vocabularies yet, and it' going to be a little bit of time. We need to have the ability to have a new code like that not break the systems.

And I think—to the point that John made about Postel's principles—I think it becomes critical to work with NIST and say—we have to be able to say, "Conform to this set of subsets. Be able to send conservatively that conforms to a standard." But if there were 200 codes that you were responsible for and we send you a code that's not in that list, you need to either have a mechanism where you can query one of these services and figure out how to incorporate it semantically, or you have to be able to say, "Display some human-readable way." And it's going to be a manual process, and it's not going to be perfect, but it isn't going to break the systems as we go.

And I think for us to be able to move the vendors and the country incrementally, we have to—and the other thing, by constraining that subset, it says, "Well, maybe of those 200 codes, I've got a proprietary system that would take me forever to map all of the SNOMED terminologies into my proprietary, but if I can focus on those 200, maybe I can get that right, and I can get started. And then these vocabulary services will become available; I can start to expand that. And I have the ability that even if it's not in my list, and I don't have the ability to query, the system doesn't break.

So I think one of the things that—and whether it shows that up in the implementation workgroup as a vocabulary certification criteria to articulate, or whether that's something that shows up in the vocabulary. And maybe you guys can work together and have a joint session where you work those things out. It seems to me that out. It seems to me that our strategy for certification should start to make sure that we not only make sure people conform to standards, but that they don't break when there are small things that happen because someone is at a different phase or a different stage of interoperability.

So I think that's an important point, and I don't care who takes the work on, but it should be something that (I think) we address as part of the certification criteria with the vocabulary …

John Halamka – Harvard Medical School – Chief Information Officer
It sounds as if that we'll be articulating some principles that will be in addition to providing subsets for vocabularies and code sets at starters, as you say, to get people on the ground floor starting to use these things as additional functionality evolves.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
This is Wes again. I'd just like to suggest that one of those principles is that the sender sends a human-readable expression of the code along with the code. That goes a long way towards using a system that's already in use for codes outside of the base set in sending lab results, on a broader basis.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, I know we need to get to our next agenda item of summer camp, but any final comments? Great. Well thanks very much, Jamie, and on to summer camp. And many of these presentations will be very short because we have just formed the workgroups, but—Stan, are you on the phone? Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay. Great. The bulk of this next segment is going to be the review of the work of the metadata workgroup, which has met three times that Stan has chaired. So, Doug?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
So, thanks. I didn't bring my clipboard or whistle today, but I'll try to get that next time. So what I'd like to do is, I just want step through some of the activities that are going on. I think there are some groups that are still forming; there are some that are storming; and there are some that are performing. And so you're going to get some of each of those categories as we go through this. So I just want to briefly update you on where we are with some of these teams, and give you a sense for the work that's going on.
We're going to start, and what I'll do is, I'll just review all of those. And then I'm going to turn it over to Stan—who can go through some of the work that he's been doing—as well as Marc Overhage, who I guess has a couple of slides about the work that you're working on as well.

So I guess the first thing is that we'll start out with the performing teams. That's the work that Stan's been doing, (this is the metadata analysis team) and it's composed of John Halamka, Steve Ondra, Dixie Baker, Wes Rishel, Carl Gunter, and Steve Stack. Since our last meeting, they have had three calls and really done a tremendous job. And I'm not going to steal Stan's thunder here, but they'll be presenting today some of the work that they did.

Remember, last month we had MDR do an initial analysis on some of the metadata standards that were out there. They've taken those. They've done additional analysis and work on it, and I think it's really going to be helpful to this committee to see the work that they've done.

The second group that we've started is the Patient Match team, and Mark Overhage has agreed to chair that particular meeting. It includes Judy Murphy, David McCallie, Nancy Orvis, Cris Ross, and Walter Suarez. They are scheduled to meet on the 20th. Right? Friday?

So they're just—they are, at this time, storming at this point, and they are going to be giving a brief presentation today. And I think after that, you guys are going to have a whole bunch of other meetings and doing fabulous things.

There's a team that is being set up right now on e-prescribing for discharge medications. Jamie Ferguson has agreed to chair that, and Kevin Hutchinson, Liz Johnson, Don Bechtel and Scott Robertson have agreed to participate. They're, right now, kind of in the organizing phase of things. We don't have any meetings that are on the schedule just yet, but we will be working over those in the course of the next couple of weeks.

And the last group, but certainly not least, is Chris Chute, who has agreed to chair the biosurveillance implementation team. We're calling these power teams because tiger teams are so 2010. And so, we've got Sharon Terry. We've got Walter Suarez, and John Derr, Ken Mendel. They're set up with some meetings in June and July; the calls are being set up. They're really going to be charged with taking a look at the CDC biosurveillance implementation—kind of reviewing that, seeing if it's conforming, and if it will meet the needs of what we need for meaningful use.

And then the last group is—there's a team that's devoted to looking at the NWHIN, and we are still in the process of selecting the team members that are on there. We have our most important person on that; Dixie Baker has agreed to co-chair that. And we'll be meeting and trying to get that group together, and they'll be charged with taking a look at some of the modularization that we're doing—trying to break down the current specifications in the NWHIN and figuring out how to include the standard services and policies and create the packages that are going to be helpful to people for achieving meaningful use.

So we anticipate there are going to be some other activities as well over the course of the summer with regard to the S&I framework. We had a discussion today about some of the directory work. I anticipate that we'll have some work to do that extends distribute query. We're working right now through the recommendations we got on the X.509 certification work as well, and trying to determine exactly where to go with that.

But that's what the current summer camp activities are. Swimming has been postponed indefinitely until we get this other work done first. But I'm not going to spend any more time. I'm going to turn it over to Stan, who is live via satellite from Orlando. And so, I'm turning to over to the happiest place on Earth.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Thank you. Let's go ahead to the next slide. Doug already announced the power team members. I would just add, we did appreciate the help of the MITRE folks, especially Lisa Tutterow, Mark Hadley, Andrew Gregorowitz, Stacy Deramis, and Joy Keeler. Next slide.

So, the charge to our team was to indentify metadata elements in three categories: patient identity, provenance, and privacy. And in evaluating possible solutions, there's really a hierarchy of preferred options, if you will. The most highly-preferred option is to find an existing standard that's available and in use and already popular that can be used. Second is an existing standard that's available but may need some modification or enhancement to meet the need. The third would be to merge a couple of standards together to meet the need. And the fourth is to create a new standard. And so in our deliberation, so far at least, we've actually always gravitated to that number one option. And in fact, I guess there would be even another principle greater than these, which you'd say, "If we could find one standard that actually did patient identity, provenance, and privacy that would be even better. Next slide.

In looking at patient identity—and this overlaps a little bit with what Mark and … and his matching team may be looking at—but the elements that we thought were essential for identity were: name, date of birth, a postal code, a patient id (where a patient id could be different things like the last four of a social security number or a driver's license number or some other number, and then address or part thereof). And Mark can probably say more, but these would be the essential ones.

And the one thing that I would say here is that we recognize that these would not be universal for everything. So there are situations when this information either doesn't exist, or the patient doesn't know it at the time, etc., that would not necessarily be handled by this set of data. But this is the first set, and it is a very reasonable set. And that's our thinking, at least to this point. Next slide.

So with the help of th MITRE folks, they did an analysis of both data elements and looked at standards that might be used to represent patient identity information, and you can see the matrix and, basically, the green boxes meant that element and its sub-elements recovered, and then the N means not it's not. So that was used in creating the next part of the analysis. Next slide.

Basically, in comparing those standards, would suggest HL7-CDAR2 as the standard conditional with a request to HL7 that we extend the name to include the display name as it exists in the ASTM and CCR. Also that we extend ID to allow for the use of a URI to act as a namespace for the identifier, as opposed to an OID, and that we eliminate licensing fees for that particular part of the header data of CDA. And our thinking on that is that HL7-CDA had better accommodates international representation of names. And then furthermore, that future support and maintenance of the standard appeared to be supported by a better process through HL7 than by the other options.

So I would ask how you want to do this now, whether we want to go through each of the things, or maybe it's best to take questions after each section so we can keep things in order?

Josh Seidman – ONC
Can you just show the sample on the next slide. Give folks a sense because, really, the design requirements were create a thin envelope that has the most basic XML constructs: name, address. So it was hard to get too philosophical about, "This is exactly what it would look like. It's in XML sample. It has the name and address, not a lot of debate where the only true debates that we had were—one, OID's aren't something that necessarily everyone likes so much, so allow URI.

To the point that Wes made about, "Maybe you should, if you transmit a code, also transmit a completely text version of that code." Well, If you're decomposing a name into its multiple component parts with

middle names and confirmation names and dashes and everything else, maybe you want to actually show the person's full text name as they would like it represented. The only other debate that we had was the date/time stamp format because there are two ISO standards for date/time stamp format, and it turns out that HL7, in every one of its standards, has used this particular format.

Whereas what I'll call generic XML'ed, as used across all industries, uses a different ISO format, which is more of a Greenwich Mean Time representation type of format—with the assumption that this was pretty much the data elements that you wanted, that it had good name support, that we'd ideally like it to be free, seemed like a reasonable suggestion. The other ones were either missing—these basics were much, much more complicated or didn't have what was perceived as a support model for ongoing maintenance.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
So who won the date/time debate?

Josh Seidman – ONC
Well I'll tell you, it's actually a funny comment, Stan. I'll share what we actually said, "Can we tell HL7 to change all of its dates everywhere to something more modern?" To which Stan provided the prudent advice, "Probably not going to be so successful doing that." We can try.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. Why does it have to be something that HL7 approves? This looks pretty generic. There must be a million places where something almost exactly like this exists; just declare it the standard.

Josh Seidman – ONC
Well again, it's a question of if you are going to maintain this thing going forward, who will maintain it? And so park it at some SDO to maintain. If the recommendation of the committee is that you don't like this date/time format, and we should add that to our series of suggestions, I'm sure we could. So, do you have comments, specifically, on your preference for date/time?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Well I think, as Stan knows perhaps better than anybody else, HL7 is struggling with its legacy issues. And having been a leader ahead of many other segments of the industry, it made decisions that the subsequent industries made in a different way. And this is, perhaps, and instance of that problem.

With that being said, I think for meaningful use purposes and to the extent that we can leverage in the spirit of PCAST tools and resources that really are industry-wide and conformant, then to that extent it would make sense to use date/times and similar types of issues that are going to interoperate not just with parochial HIT standards, but with information standards globally.

John Halamka – Harvard Medical School – Chief Information Officer
So just to amplify on what Chris said is that some of us (and I know you guys spend lots of time doing XML constructing—if you use a tool called XMLSpy, XMLSpy will represent this particular string of 19600427 as just that. It's not a date/time. It's just characters. Whereas if you were to use what you suggest, which is the more modern ISO standard for date/time, it will enforce a date/time format.

Again—as Mark is shaking his head—this was not something that kept us up at night. I was just being completely transparent with all of the issues that we discussed because this was one that didn't have huge amounts of emotion around it. So, Mark, comments?

M
I was just going to say, there's other things I'd be more curious to hear about, for example, country code. You would think we'd want country represented a minimum. And then I was also curious—the address being a blob and the lack of codes for the city and state. It kind of surprised me.

John Halamka – Harvard Medical School – Chief Information Officer

Yes. So we didn't specifically discussed street address being broken into multiple components or a specific vocabulary and code set for state. And, Stan, do you even know? Does the CDA header specify a code set for state, or does it support country?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
It supports country. And yes, it has essentially a pick list for state. So, yes.

M
…

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes. Just another comment on the advantage of the date/time that's part of the standard semantic Web style. John has articulated this date and time format. The number is a format that everybody who is using HL7 version 2.3 understands and already has parser for, and is probably processing millions of transactions a day using this format.

This is in use to the parser that exist for just the way that the data is coming from some laboratories, and everything is being exchanged as an HL7 message—2.3 or CDA—is already in this format, and people know and use it and understand it, so that's the other side of being different.

And I guess the overriding principle, to me, comes back to what's been stated several times, you can argue these things to death, and in the end the greatest value is that we choose one and stick with it. And people will accommodate the gauge of the railroad eventually so that we're all interoperating.

John Halamka – Harvard Medical School – Chief Information Officer
Doug, did you have your card up?

Doug Fridsma – ONC – Director, Office of Standards & Interoperability
Yes, hi. I was just going to echo what Stan just said. I think these are all excellent comments, and I think we'll try to capture those things as well. But the charge, really, was to come up with the minimum set that was simple as a starting point. One can imagine—and oftentimes XML parsers are able to do this—is that if there's an element it doesn't understand, it throws it out and keeps going. It understands it. It tries to incorporate it.

And that may be something where the minimum set says we have city, state, postal code, but if somebody includes a country code and you know what to with it, maybe that would be okay. But if not, it's maybe not part of that set. And I think that's idea of anytime, if there's a new use case that says we need to break up street address into number and streets and things, we can consider those things as well. But this was really aimed at being the minimum set that would get us where we needed to go.

John Halamka – Harvard Medical School – Chief Information Officer
Kevin?

Kevin Hutchinson – Prematics, Inc. – CEO
Just a quick comment on the same kind of issues that have been brought up by Mark as well, when we were implementing medication history as an example, what we found helpful were things like maiden names. But now only maiden names, people that have been married multiple times, making sure that there is a connection between 'x' names when you're wanting to actually get the demographic information right as a historical viewpoint.

I know this is just an example, but it does make it sound a little more complex than the simple name, city, address kind of mentality, especially when you can look at this from a longitudinal medical record. We found that very key.

Josh Seidman – ONC

And purely out of curiosity, Stan, do you know if the CDA header supports that concept of maiden names?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes. This is a simple example. The name structure allowed, basically, you to have all of these name parts, and then you can additionally actually tag them and say—some people call this the first name, and other people call this the maiden name, and other people call this—yes. So you have that flexibility within the standard.

Josh Seidman – ONC
… reasons that we chose the CDAR2 was because of a lot of the flexibility around names that didn't exist in other standards.

John Halamka – Harvard Medical School – Chief Information Officer
One more question from David. Does family name account for suffix? If you are a junior, is that supposed to be part of the family name, or do you just suggest dropping that?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
No, it's a separate part, not shown in the example, but that's a separate part.

John Halamka – Harvard Medical School – Chief Information Officer
So this isn't the complete list?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
It's not complete. This is an example.

John Halamka – Harvard Medical School – Chief Information Officer
Right. So again, the proposal here is that CDAR2 and that it does include more than the sample, but this just shows you how simple it can be.

Well, let us move on to provenance. And I think that you all foresee a very similar, simple XML example for provenance. So, Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes. In the PCAST report, it identifies many needs for applications. And talking about provenance, basically it's who created this data, and how can I be sure? So we wanted to determine the source or owner of the information that person's organizational affiliation, and prove the data was not subject to tampering and provide non repudiation of tabbed data elements. Next slide.

So after some discussion, we came down to a fairly basic model saying, "I'm not trying to send the whole history of this data element in a message." What I would send is, "Who is it that's sending me this data," and a unique identifier for this particular instance of the data, and when that message was sealed or closed, and a signature that binds the metadata to the companion information for non repudiation. And so the data elements that we identified as being important of provenance were the tagged data element, (which is the unique identifier for this instance) the time stamp (which is when this tagged data lealest was created—when this particular message was created, and then the affiliation.

There's some discussion, we for sure want to know the institution and maybe the sub department so that we know that it's Intermountain Healthcare Department of Radiology, or that level of identity where further discussion was value in having an optional element that would tell you the responsible radiologist's name. And then the final part was the signature that binds the metadata to the contained information to provide non-repudiation and integrity. Next slide.

Again, the analysis of potentials standards in this slide builds. You have, basically, healthcare standards and provenance standards, and other standards that can contribute to this. And again, without going into all of the discussions that we had about and all of the analysis that MITRE did. Next slide.

The suggestion was that we use HL7-CDAR2 header as the standard, which would contain a TBE identifier or a time stamp, an optionally, a more gradual affiliation. So if we did want to identify a person, it would go there. Otherwise, it would be the distinguished name down in the X.509 certificate. And so the metadata should point to the end of the record in the enterprise-level provider directory if we're identifying just the institution or the entity if you are the responsible entity as an organization. And then we would have the X.509 certificate that contains the actual affiliation as a distinguished name.

And again we have—next slide—is an example of that would look like, roughly.

John Halamka – Harvard Medical School – Chief Information Officer
There was a—please, go ahead, Stan.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I was ready to ask for questions or additional comments.

John Halamka – Harvard Medical School – Chief Information Officer
Let me just capture the rich discussion that we had. Suppose, Doug, someday that there is federated entity-level provider directory that is addressable by a URI. Well, one of the things that would be nice is if you had a directory to leverage it and to say, "Okay, I am signing this lab transmission. Beth Israel Deaconess Department of Pathology is sending it to you, and here is the URI of us in a provider directory somewhere.

But then again, to the point that Wes made, so what if we decide to merge? If we rename ourselves? If we go out of business? You might want to include a text-based readable representation of who we are at this moment in time that we are signing the transaction. So the three components of provenance you can see here are: an id, (which optionally can point to some provider directory via an arbitrary URI. And then an author or affiliation that could be—but it's probably more likely going to be an entity, not a person. But maybe you 't want to put in a person. So provide that XML should you with to do that.

And then of course, I am signing the envelope with a My Certificate so that there is some notion of who I am and non-repudiation, and will ensure the distinguished name and the certificate matches any text representation that we put in the provenance data.

So that was it. Pretty, again, simple XML format—yes, Mark?

M
… discussion along the way about granularity of the signing organization. I heard, not the individual. We certainly have organizations in Indiana that do business with 18 hospitals and many thousands of docs who have one tax id and one registration in the hospital registry for the state, others are broken up by the different institutions. Any discussion about how granular we would hope those to be?

John Halamka – Harvard Medical School – Chief Information Officer
So what we had talked about was that you had—let's imagine an entity, and conceivably a sub department of that entity and an individual within that sub-department. So those were the hierarchy we talked about. But if you pointed to a provider directory of arbitrary complexity, you could really point to any level of granularity you wanted, and since it's a distinguished name on a certificate, you could get a certificate for any entity, large or small, that you wish.

M
Sure. And I guess my point was just you could easily end up with something that was tagged as coming to provenance as it come from IU Health. Which of the 196 laboratories is that, and how do you begin to —if you have a question, one of the reasons wanting a provenance is usually to backtrack on some level. Now you would hope the entity would have some way if you said, "Okay Mr IU Health, which laboratory did this come from," they might b able to answer that question.

John Halamka – Harvard Medical School – Chief Information Officer
Well, Stan and Dixie, I think what we had said was exactly your point: that we wished the person responsible for the sending of the clinical data to have their representation, so should they need to be reached, they could be. But we didn't have—other than more of a statement of policy direction—we didn't' specifically say it must be down to your mail stop.

Stan, any comment on that?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I would just say we focused on making sure that the structure was flexible enough to represent it at whatever granularity was appropriate, and we didn't talk so much about what the policy would be. And I think what you're saying is that we need to probably spend a little more time to formulate a reasonable policy that we would require because the goal is to make a choice that will back a responsible party.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. That's one goal. The other goal is to make it tamper-proof, which is achieved even if the granularity is coarse.

John Halamka – Harvard Medical School – Chief Information Officer
Linda

Linda Fischetti – VHA – Chief Health Informatics Officer
Hi, Stan, Linda Fischetti, VA.—one quick question—have you talked with Brad or some of the other GS1 representatives that are there at the HL7 Orlando meeting? There may be some utility in some of how they identify entities that would be useful to you. Thank you.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
No I haven't, but that's a good recommendation.

John Halamka – Harvard Medical School – Chief Information Officer
Any other comments on this? So again, per the 'keep it simple' principle, this is pretty straightforward XML, no OIDs, URIs, standard tools, and the concept would be and envelope would contain this, and you could put any payload in that envelope that you with.

Okay. Well, Stan, no further questions. We're tiring them out. So on to privacy, and the good news is we don't have an answer on privacy, so there's nothing to talk about. Go ahead.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
In spite of that, we're going to talk about it a little bit. The goal, again, is to determine what privacy metadata are needed for each CDE, and we're still discussing it, but there are a couple of, I think, interesting principles that we would just like to expose, and people may have comments. So, next slide.

So privacy policies included content metadata, which includes the data type, sensitivity, and coverage. I'll get into a little bit of complication here because the PCAST report itself I don't think actually talks about content metadata, it talks about attributes of the contained data. And so someplace, obviously, in the outer envelope, you want to have something that says this is a discharge summary, or this is the vital signs, or this is a chemistry panel, whatever it is.

But then additionally, you want to have sensitivity coverage and there's information if you're—and go ahead and build this slide because the request metadata really is out of scope for what we're doing here. So that's not a consideration. But also, approaches for storing policies—the ideas is that you could have the policy that says how this policy can be accessed in each element of the data. But as we discussed in the previous hearings and in understanding what people really wanted, they want to be able to change the policies as the patient would dictate (access policies). And so you don't want to fix the policy in time by including it in each data element. At least, that didn't seem feasible to us.

And so the idea is (which is what we came to) that what you would do, basically, is you would contain a pointer to a place where the policy resides, and you would then be able to at the time use of the data—reference that policy and know the current policy for that data element. So go ahead and next slide, but what it'll really do is build this slide.

So we described sending—the exact set of security in each element was not feasible, but we wanted this data element to be able to point to a place where that policy could be dynamically changed, and then build again. Next slide again.

Just, again, to clarify that descriptions of the request metadata are really out of scope for what we were doing in this first description. So next slide.

Again, what we described as suggested elements in the metadata for privacy were a policy pointer, a URL that indicates which privacy policy governs the release of that particular TDE, and then content metadata, which would be a data-type of the information—a category if you will—of the clinical data, the sensitivity, which indicates special handling, and then coverage, which is who paid to acquire the information, or other kinds of things.

And this is where we got to, and this is not resolved. So next slide, and then I think we're to questions and thoughts again. Again, we have the analysis of which of those data elements are parts of which standards, but we haven't determined to finalize the details of this particular discussion yet. Next slide.

John Halamka – Harvard Medical School – Chief Information Officer
So what we didn't want to do was create disclosing clinical information in the envelope—something that says, "Hey, this patient is HIV positive. You better get a special consent before you look inside. So basically this metadata you could see. It's a patient's id, it's provenance, and then some policies like 'special handling require'—nothing disclosing specifically. So we're still working on that, and obviously we'll have another call scheduled to come back with some recommendations, but there's a series of standards under evaluation.

Comments?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. I have a question.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Please. Go ahead.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
And this may not be possible if you want to be completely non-disclosing, but it seems like it's feasible that a patient might want to change what they consider to be sensitive at some point in the future. They may not know at the time that they considered something sensitive, and then they discovered that, in fact, it is sensitive for them—for a particular reason, occupation or there's a variety of reasons—so it would seem like in a fully-normalized model, the only thing that would be in the tagged data element itself is, "What is this item," and then some external reference would say, "What kinds of items do I consider sensitive (question number one)? And then question number two, what policy do I want to apply to those sensitive items? In other words, who am I willing to show them to.

You pushed the sensitivity down to the time of care, I'm not sure that that will work in all cases. Maybe that's compromise that you have to accept. But it seems a little bit like a denormalization. It's not quite right.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
No, that's good input. In a sense, you're saying we should so the same thing for sensitivity that we did for the policy and make it dynamic, and make a pointer do it rather than trying to create it statically with this instance.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes. Although I think that then means that the data element needs to declare what kind of data it is unless you're going to keep a dictionary of every single data element that you've ever see—in other words, if it says this is an HIV test, these days that's not revealing anymore because everybody has them, but you could say there are certain things where just the definition itself if revealing. I'm personally not convinced that's a problem, frankly, because I think this all has to be protected anyway. But that would be the tradeoff.

John Halamka – Harvard Medical School – Chief Information Officer
Good point. Kevin?

Kevin Hutchinson – Prematics, Inc. – CEO
Just a short comment—I remember when we launched Katrina, trying to help out with the medication history, and we had to go to the lowest common denominator on security because, one, we had to do it very quickly, but we had to deal with state law. And so as I'm thinking through this privacy standard and the sensitivity of that information, there's going to be a need in this of flexibility to be adjusted almost on a state by state basis, depending on what those state rules and regulations (not just the federal) that are going to be enacted.

So it's something to keep in mind as we pursue a standard around it.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Right, because we had looked at—in existing standards—existing code sets to describe levels of sensitivity, and of which there were 10 or 20 different sensitivities. It certainly wouldn't cover every potential policy that every state might make.

John Halamka – Harvard Medical School – Chief Information Officer
Yes, Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research
Okay. If I could just add something to that, one thing I was just whispering to Doug, but if I figured I'd say it publicly, is that from a federal perspective HHS and HIPAA rules, we have said that all health information is sensitive, and people have different sensitivity levels, so we treat all health information … under HIPAA. And I understand that state laws are different, and that's a challenge.

One thing I would just suggest is that for sensitivity—think about how it might enable a patient's preference on sensitivity to being a flag, even if it's just an on/off flag, so that somebody might find something sensitive that their state law doesn't require extra consent for. And if they've actually asked for it not to be shared, that there's a way of having the patient preference being the on/off, as well as the state law being an on/off, or the federal law being the on/off for sensitivity.

John Halamka – Harvard Medical School – Chief Information Officer
Very reasonable. Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I just want to say one comment about David's comment about how the scheme has to allow for patients to change their minds. But at the same time, the data that are exchanged need to be bound to the rules that were in force when they were exchanged because it will have an impact on the organization in ——the way the information is used in making decisions, etc.

John Halamka – Harvard Medical School – Chief Information Officer
So if I consent for my data to be exchanged for an emergency care visit and three years later redact that consent, and care has already been delivered based on my initial consent, and it was already incorporated into a record, that would be slightly challenging to undo.

So more to come on this. We don't have answers for you today, but boy will we have a fun discussion next time. And I know we're running very short on time. Thanks very much, Stan. Did you want to quickly get any comments from Mark on summer camp?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
This is Stan; I need to take off.

M
Great.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Stan, thanks. I just want to say thanks to Stan and the team. We gave them impossible deadlines and a really fairly big task to take a look at. They were able to hone in on the critical elements, come up with something that I think makes a lot of sense just looking at it. It has that face validity that I think is important, and I just want to thank the team for all of the work that they did. It's really nice.

John Halamka – Harvard Medical School – Chief Information Officer
Okay. Well again, my thanks, and John's as well, for all of the hard work that went on around these separate activities. Let me turn to Judy Sparrow with time for public comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
Sure, it is that time. So if anybody in the room wishes to make a comment, please queue up to the mic. Anybody in the room care to comment? Let's just wait a few seconds for the phone.

Jonathan Perlin – Hospital Corporation of America – CMO & President
… calls, we greatly appreciate everybody's intense concentration on a variety of complex topics. John and I were chatting at lunch and saying that the discussion was particularly engaged. I think I was reflection on this. It's a big difference from when we started as it's getting real. It has traversed that divide from what might happen to what is happening, and I think that increases everyone's sensitivity and proximity to very real examples such as that one John just offered in terms of at first they might change, and their rating of sensitivity of information.

So thank you very much for the engagement, the intensity of discussion. We have a lot of work to do this summer, and many thanks in advance for that. And good luck with all of your activities in your day jobs because I know that that side of your activities is very much connected with this side in terms of making it real. So thank you for that as well.

I believe, if there's no other business that anyone would like to bring forward, then we stand adjourned until our next meeting. Thank you all very much, and thank you ONC and Judy.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks so much.

Public Comment Received During the Meeting

1. CDS attributes need to be coordinated with the needs of comparative effectiveness research, systematic reviews and clinical practice guidelines. How is this being addressed?

2. I could also see some standards being developed that focus on the needs of CDSS, and I would be very interested in participating in these discussions.

3. I would like to comment on subsets. If subsets are used there needs to be a process to keep subsets up to date for future. Some current subsets i.e. UMLS SNOMED to ICD-9 map is current out of date.

4. I would like to comment on RXNorm and its use in Quality Reporting. Currently the Quality Reporting specifications for stage 1 only includes generic drugs, brand drugs are not in the specification which poses a problem for accuracy of reports and adoption. This issue must be resolved with any quality reporting specifications for stages 2 and 3.

5. I would appreciate easy access to the information about CDSS attributes. Can I suggest that a specific place be created for this information?

6. I would like to add a comment related to quality reporting. It is important that standards for Quality reports and other areas of MU such as CCD exchange use the same standards where possible. For example if SNOMED is used for Quality reporting for Lab then SNOMED should be used for interoperability. This will eliminate the need to do complicated dta maps and to keep the maps up to date.

7. Problem lists have been a big struggle for physicians in the hospital environment. Common issues are: "who is responsible" i.e. attending, hospitalist, some hospitals want nursing to "own" it. I think that creating an "operational definition" and clear intent of the problem lists will assist with adoption. Right now nobody wants to "own it in a hospital environment.

8. I would like to make a comment related to problem list. The UMLS problem list map from SNOMED to ICD-9 is not up to date. Many of the ICD-9 codes are no longer valid. It is imperative that standards are kept up to date. Care and feeding of standards needs to be incorporated into the future.